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PROVISIONAL APPLICATION COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION under 37 CFR 1.53 (c).

	Docket Number	4398-313	Type a plus sign (+) inside this box→	+

INVENTOR(S)/APPLICANT(S)

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22581 60/533214 U.S. PTO 123103

TITLE OF THE INVENTION (280 characters)

COMPACT ORONASAL PATIENT INTERFACE

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☒ Specification	Number of Pages	17	☐ Applicant claims "small entity" status. ☐ "Small entity" statement attached.	
☒ Drawing(s)	Number of Sheets	28	☐ Other (specify)	

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The invention was made by an agency of the United States Government or under a contact with an agency of the United States Government:

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Respectfully submitted,
SIGNATURE _____ DATE **December 31, 2003**

REGISTRATION NO. *(if appropriate)* 38,009

TYPED or PRINTED NAME Paul T. Bowen

☐ Additional inventors are being named on separately numbered sheets attached hereto.

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U.S. PATENT APPLICATION

Inventor(s): Joanne Elizabeth Drew

Invention: COMPACT ORONASAL PATIENT INTERFACE

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SPECIFICATION

804220

COMPACT ORONASAL PATIENT INTERFACE

FIELD OF THE INVENTION

[0001] The present invention relates to a patient interface for use between a patient and a structure to deliver a breathable gas to the patient, such as is used in gas delivery systems for respiratory therapy. Examples of such therapy are Continuous Positive Airway Pressure (CPAP) treatment, assisted respiration or Non-Invasive Positive Pressure Ventilation (NIPPV).

BACKGROUND OF THE INVENTION

[0002] Comfort and effectiveness remain a continuing challenge for engineers and designers of the interface between a mechanical ventilator and a patient. Such patient interfaces are currently employed for a variety of purposes including the delivery of non-invasive ventilation or for the delivery of pressurized air to persons who suffer from sleep disordered breathing conditions such as Obstructive Sleep Apnea (OSA). In non-invasive positive pressure ventilation, a supply of air at positive pressure is provided by a blower to a patient interface through an air delivery conduit. The patient interface may take the form of a nasal mask, nose & mouth mask, full face mask or nasal prongs.

[0003] A mask may comprise (i) a rigid or semi-rigid portion which attaches directly to the air delivery conduit and (ii) a soft patient contacting portion. The rigid or semi-rigid portion, known as a shell or frame, may define a nose-receiving cavity, or a mouth covering chamber. Other forms of patient interface, such as nasal cannulae, comprise a pair of nasal prongs, nasal inserts or nozzles.

[0004] The soft patient contacting portion is typically known as a cushion or membrane and is generally shaped during manufacture to match the facial contours of a patient in order to provide the optimum seal.

[0005] An inherent characteristic of patient interfaces such as nasal masks or nozzle assemblies is that they do not seal the mouth region. A number of patients thus find that during sleep when muscles relax, mouth leak may occur. Alternatively some patients are naturally mouth breathers and thus find a nasal patient interface ineffective. Mouth leak is undesirable as among other difficulties, it may result in noise, increased treatment pressure to compensate for the leak or an increased load on the nasal passages and potentially nasal obstruction or a runny nose.

[0006] Patient interfaces such as full face masks or nose and mouth masks address this issue by sealing around both the nose and the mouth. Since nasal bridge anthropometry varies greatly between patients, the soft patient contacting portion or cushion must adapt to the shapes of individual patients. Typically this is not achieved for the entire range of patients and some form of leak occurs. The problem is heightened during sleep when the jaw moves and the head position changes. This action can often serve to dislodge the mask and cause leak. Since leak can be noisy and results in less-effective treatment, users often compensate by tightening the headgear more than is required. This is detrimental for patient comfort and can cause skin breakdown.

[0007] A further problem encountered by patients who are using full face, nasal or nose and mouth masks is that the portion of the patient interface that seals around the nasal bridge prevents the patient from wearing spectacles. Additionally it may give the sensation of being closed in, leading to a feeling of claustrophobia, particularly when combined with a mouth-

sealing portion. A further disadvantage is that any leaks that may occur can affect the sensitive area surrounding the eyes.

[0008] One form of nasal assembly known as a nasal puff is described in U.S. Patent No. 4,782,832 (Trimble et al.). This device has a pair of nasal puffs together with a plenum chamber held in place with a harness assembly adapted to be worn over the head of the patient. The device does not provide a mouth seal.

[0009] Another form of known nozzle assembly is described in U.S. Patent No. 6,431,172 (Bordewick et al.). The patent discloses a device with nares elements mounted on an inflatable plenum chamber. Again this does not provide any structure for sealing the mouth.

[0010] One typical example of a known nasal mask is described in U.S. Patent No. 5,243,971 (Sullivan et al.). This has a ballooning seal in order to fit the patient's nose and facial contours but does not provide a mouth seal. The contents of this patent are hereby incorporated by cross-reference.

[0011] International publication number WO 01/97893 A1 (Frater et al.), the content of which is hereby incorporated by cross-reference, describes a mask system for delivering air to a user including a suspension mechanism. This suspension mechanism allows relative movement between a face-contacting portion and a mask shell.

[0012] A known example of a full face mask is described in U.S. Patent No. 6,513,526 B2 (Kwok et al.), incorporated herein by reference in its entirety. Whilst providing a facial contour and sealing mechanism that incorporates both the nasal and mouth, this mask cannot flex to adapt to changes in jaw movement and head position throughout the night.

[0013] A known example of a nose and mouth mask is described in U.S. Patent No. 5,560,354 (Berthon-Jones et al.), the content of which is hereby incorporated by cross-reference.

[0014] U.S. Patent Publication No. 2002/0069872 A1 (Gradon et al.) describes a mouthpiece which seals the oral cavity against 'mouth leak'. This mouthpiece includes both intra-oral and extra-oral sealing means and can be kept in place without the need for straps. International patent WO 01/95965 (Gradon et al.) describes a similar mouthpiece for supplying humidified gases to a user.

[0015] U.S. Patent No. 6,571,798 B1 (Thornton) describes an oral device for improving a patient's breathing together with a connecting post that provides a standard interface to a CPAP patient interface. The oral device is said to extend the lower jaw of the patient and thus open the breathing passage. The oral device is clenched between the teeth which may lead to discomfort and if mask pressures are high can lead to the slow creep of gums around the teeth due to the sustained load..

[0016] U.S. Patent No. 1,873,160 (Sturtevant) describes a cylindrical air chamber held in position by a mouth portion that extends between the lips and teeth. The mouth portion may prove irritating and lead to discomfort when used for long periods.

[0017] A problem with patient interfaces which incorporate oral appliances is that they can be uncomfortable for patients. Therefore, a need has developed in the art to address the problems of the prior art.

SUMMARY OF THE INVENTION

[0018] In accordance with a first aspect of the invention there is provided a comfortable, effective patient interface which provides a supply of air or breathable gas to a patient's nasal passages and which prevents or reduces mouth leak.

[0019] In accordance with a second aspect of the invention there is provided a patient interface which can accommodate movement of the jaw of the patient.

[0020] In accordance with another aspect of the invention there is provided a patient interface that provides an effective seal with both the patient's mouth and the patient's nasal passages.

[0021] In one form the invention comprises a mouth covering chamber, a nozzle assembly and a structure to provide flexibility therebetween.

[0022] Another aspect of the invention relates to reducing contact area when compared to most known full face masks. This allows a far reduced headgear tension to be applied, significantly improving patient comfort. Patient comfort is further enhanced since the patient is less likely to feel claustrophobic, particularly with the removal of any mass that is close to the eyes.

[0023] In accordance with another aspect of the invention there is provided a patient interface adapted to connect to an air delivery conduit.

[0024] In accordance with another aspect of the invention there is provided a patient interface comprising a first chamber which incorporates a mouth covering chamber, a second chamber which incorporates a nozzle assembly and a flexible element connecting the first and second chambers.

[0025] In accordance with another aspect of the invention there is provided a patient interface comprising a mouth covering chamber, a pair of nozzles and a flexible attachment member therebetween.

[0026] In accordance with yet another aspect of the invention there is provided a patient interface comprising a mouth covering chamber and a pair of nozzles flexibly attached thereto. The mouth covering chamber incorporates a rigid portion defining the mouth covering chamber and a resilient or compliant patient-contacting portion. The pair of nozzles are mounted upon the patient-contacting portion.

[0027] In accordance with yet another aspect of the invention there is provided a patient interface comprising a mouth receiving assembly and a pair of nozzles flexibly attached thereto. The mouth receiving assembly incorporates a rigid portion defining a mouth covering chamber, a gusset portion and a patient-contacting portion. The pair of nozzles are mounted upon a flexible component of the patient-contacting portion.

[0028] In accordance with yet another aspect of the invention there is provided a patient interface with a strap routed around the top of the ears.

[0029] These and other aspects of the invention will be described in or apparent from the following detailed description of preferred embodiments, in which like elements designate like parts.

BRIEF DESCRIPTION OF THE DRAWINGS

[0030] Figs. 1a-d show a dual chamber patient interface in accordance with a first embodiment of the invention.

[0031] Figs. 1e-1h illustrate various embodiments as to connection between the upper and lower chambers;

[0032] Figs. 2a-c show a dual chamber patient interface in accordance with a second embodiment of the invention.

[0033] Figs. 3a-c show a dual chamber patient interface in accordance with a third embodiment of the invention.

[0034] Figs. 4a-c show a single chamber patient interface in accordance with a further embodiment of the invention.

[0035] Figs. 5a-d show front and rear views of a further embodiment of the invention.

[0036] Figs. 6a-b show a single chamber patient interface with mouth gusset portion in accordance with a further embodiment of the invention.

[0037] Figs. 7a-b show views of a single chamber patient interface with mouth gusset portion in accordance with a further embodiment of the invention.

[0038] Figs. 7c-f show views of an alternative embodiment of a single chamber patient orifice in accordance with a further embodiment of the present invention.

[0039] Fig. 8 shows a patient interface in accordance with an embodiment of the invention connected to a headgear routed around the top of the ears.

[0040] Fig. 9 shows a patient interface in accordance with an embodiment of the invention connected to different forms of headgear routed around the top of the ears.

[0041] Figs. 10-12 illustrate various headgear arrangements according to further embodiments of the invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0042] Figs. 1a-1d illustrate a first embodiment of the present invention. As shown in Fig. 1a, a headgear assembly 1 includes a patient interface having a dual chamber assembly 10 including an upper chamber 12 and a lower chamber 14. As shown in Fig. 1a, the lower chamber 14 is in a disconnected position, while Figs. 1b-1d shown the upper and lower chambers in a connected position.

[0043] Referring to Fig. 1a, the upper chamber 12 includes a nozzle assembly 16 supported by a frame including a first connector on each lateral end thereof, as described in U.S. Provisional Patent Application No. 60/488,810, filed July 22, 2003 and incorporated herein by reference in its entirety. The nozzle assembly 16 is secured to the frame via a clip 18 which in this embodiment supports a pressure measurement port 20. The nozzle assembly 16 may include a pair of nozzles 17 (see Figs. 1c and 1d).

[0044] One or more inlet conduits 22 is supplied with breathable gas under pressure via a joint 24 coupled to an air delivery tube, which in turn is communicated with a blower or air delivery device. The lower chamber 14 is connected to the joint 24 via an inlet conduit 35. The joint 24 may include three branches (see Fig. 1b) for connection to the inlet conduits 22 and 34.

[0045] Each inlet conduit 22 is connected to an elbow connector 26, which is preferably connected to yoke 28 of strap 30 of headgear assembly 31 via a locking portion 32. Each elbow connector 26 is coupled to a second connector 34. Each respective first connector of the frame may be selectively rotated with respect to the second connectors 34 to allow the nozzle assembly 16 to be adjusted according to patient requirements, to achieve the best fit.

[0046] As best shown in Fig. 1a, where the upper and lower chambers are disassembled, a first portion 36 of the lower chamber 14 may be connected to a second portion 37 of the upper chamber 12. Connection may be achieved via a conduit 41 (See Fig. 1e), or preferably a flexible element that connects the upper chamber 12 to the lower chamber 14. The flexible element may comprise one or more thin silicone conduits through which air can pass. It may take the form of any other flexible element through which air can pass however, examples including a spring 43 (Fig. 1f), bellows 45 (Fig. 1g) or piston mechanism 47 (Fig. 1h). The flexible element provides a range of adjustment to adapt to the different geometry of a wide

range of patients and in addition allow for any movement of their jaw and head position during sleep. The conduit need not be flexible if adjustment can occur via flexibility of the cushions of the upper and lower chambers.

[0047] Connection between the upper and lower chambers may take several forms, keeping in mind that one main purpose is to maintain the position of the upper chamber 14 relative to the patient's mouth. To that end, the connection may take the form of a mechanical fastener, such as VELCRO®, snaps, connectors, etc. For example, the top or second portion 37 of the upper chamber 14 may include a hook portion of VELCRO®, while the bottom or first portion 36 of the upper chamber 12 may include the loop portion of VELCRO®. In other forms, the connection may be provided via metal or plastic rivets and/or by use of adhesives. In the case of rivets, flexibility could be provided by virtue of the compliant and flexible portions of the cushions of the respective upper and lower chambers that are fastened together. In other forms, the lower chamber 14 may be connected to a portion of the headgear or to the inlet tubes 22. Moreover, it is not necessary that air can pass between the upper and lower chambers 12, 14, as each has an independent source of pressurized air.

[0048] As shown in figures 1a-1d, the lower chamber 14 includes a rigid polycarbonate frame 38 which defines a mouth covering chamber 40 (see Fig. 1c) and a soft (e.g., compliant, resilient) silicone cushion 42 which contacts the patient and forms a seal. The lower chamber 14 closely resembles the mouth chamber and mouth cushion described in U.S. Patent No. 5,560,354, the contents of which are hereby incorporated by cross-reference. However it may take a variety of forms, such as described in U.S. Provisional Patent application No. 60/483,622 filed 1 July 2003. The cushion 42 may be attached to the frame 38 by connecting a base edge of the cushion 42 to the frame 38, e.g., via adhesives and/or a tongue and groove

arrangement. In another form, connection may be achieved by stretching the cushion 42 over the outer edge of the frame 38.

[0049] The inlet conduit 35 is structured to deliver breathable gas into the lower chamber 14. The inlet conduit 35 may be inserted into an aperture of the frame 38, in which case the tube 35 may be held in place by friction alone, as best shown in Figs. 1b and 1d. Alternatively, the inlet conduit 35 may be connected to a swivel assembly (not shown) which in turn is connected to the frame 38. In another alternative, one or more suitable headgear straps (not shown) can be used to support the lower chamber 14 such that it can move or pivot relative to the upper chamber without the need for connection thereto or a flexible element.

[0050] Figures 2a and 2b show a second embodiment of the invention. In this embodiment, the lower chamber 14 does not have a direct inlet conduit, like the inlet conduit 35 in Fig. 1a, but instead the air is directed to the upper chamber 12 via the inlet conduits 22 only. Air travels through the flexible element, i.e., through first and second surfaces 36 and 37, from the upper chamber 12 to the lower chamber 14, for example, thus allowing both nose and mouth breathing. Fig. 2b best showed the position where the flexible element would be located between the first and second surfaces 36, 37.

[0051] Fig. 2c shows one example of how the upper and lower chambers 12, 14 may communicate with one another. A mechanical fastener 90 includes first and second parts 92 and 94. The first part 92 may take the form of a thin plate attached to an inside surface 37a of the second part 37 formed on the upper chamber 12. The first part includes an aperture 96. The second part 94 may include a thin plate positioned on the inside surface 36a of the first part 36 formed on the lower chamber 14. The second part 94 includes one and preferably a plurality of arms 98 extending through the upper and lower chambers 12, 14. The arms 98 are resiliently flexible so that shoulder 100 on each arm 98 may be secured against a top

surface 92a of the first part, thereby locking the entire assembly together while allowing gas to flow between the upper and lower chambers 12, 14. The arms 98 may be formed so as to cut through the upper and lower chambers 12, 14 upon assembly, thereby creating the through hole. The assembly may provide for multiple holes if desired.

[0052] In Figs. 2a and 2b, a plug 48 covers an aperture of the frame 38 where an inlet conduit could be placed. Therefore, the joint 24 in Fig. 1a need not include a separate branch for the conduit 35, or the branch could be plugged.

[0053] In a third embodiment of the invention, as shown in Figs. 3a and 3b, inlet air is directed directly to the lower chamber 14 through a swivel assembly 50. The upper chamber 12 does not have any inlet conduits but instead the air is directed to the upper chamber 12 by traveling through a conduit extending from the first surface 36 to the second surface 37. The use of a swivel assembly 56 has the advantage that the inlet conduit (not shown, but connected to end 52 of swivel assembly50) can be routed from any direction. Further, nozzle assembly 16 need not be provided with second connectors 34 and elbow connectors 26 as shown in Fig. 1a. Instead, a pair of plugs 54 may be placed into each end of the nozzle assembly 16, as described in U.S. Provisional Patent Application No. 60/529,696, filed December 16, 2003 and entitled "Nasal Assembly", incorporated herein by reference in its entirety.

[0054] Figures 4a-c schematically show a fourth embodiment of the invention. In this embodiment, the mouth covering chamber 40 and the nozzle assembly 16 form one chamber with inherent flexibility of the soft silicone cushion 42 upon which the nozzles 17 are mounted providing for movement and changes in alignment between the two. This embodiment of the invention achieves the advantage of minimizing the volume of the patient interface which is positioned between the nares and the upper lip.

[0055] Figs. 5a-5d illustrate yet another embodiment of the invention. As can be seen from Fig. 5a, a swivel assembly 50 provides air from an air delivery tube (not shown) and supplies it to the mouth covering chamber 40 (best shown in Fig. 5b). The cushion 42 is connected to the rigid frame 38 of the mouth covering chamber 40 via a cushion clip 56. As best shown in Fig. 5b, the nozzles 17 are connected or provided directly to the outer face contacting portion of the cushion 42 which takes the form of a thin silicone membrane 58. The membrane 58 performs the dual function of forming a seal around the lips of a patient and additionally supporting the nozzles 17. The inherent flexibility of the membrane 58 provides a range of adjustment to adapt to the different geometry of a wide range of patients and in addition allows for any movement of their jaw and head position during sleep. It should be noted that whilst this embodiment describes nozzles 17 of a similar form to those disclosed in US Provisional Patent application No. 60/488,810 filed 22 July 2003, the contents of which are hereby incorporated by cross-reference, they may take the form of any nasal prongs insertable into each nare. As shown in Fig. 5d, the patient interface can easily be attached via clips 60 to a headgear assembly 31 in order to secure the patient interface to the patient. The headgear 31 includes an intermediate strap 31a extending between clip 60 and connector 33. The clip 60 and its connection to frame 30 resemble the clip/frame described in U.S. Patent Application No. 10/655,603, filed September 5, 2003, incorporated herein by reference in its entirety.

[0056] Figures 6a-b schematically illustrate a fifth embodiment of the invention. In this embodiment the patient interface includes a mouth covering chamber 40 incorporating a rigid frame 38, a gusset portion 62 and a soft cushion 42. The nozzles 17 are connected directly to the outer face contacting portion of the cushion 42 which takes the form of a thin silicone membrane 58. The gusset portion 62 includes a flexible membrane and has a first side

attached to the frame 38 and a second side attached to the cushion 42, as shown in Fig. 6b. Pressure within the patient interface acts upon the increased surface area of the gusset portion 62 projected on the patient's face so as to provide a sealing force for the soft cushion 42 against the patient's face. In addition the gusset portion 62 acts to effectively isolate or decouple the rigid frame 38 from the soft cushion 42. In these respects, the gusset portion 62 acts in a similar manner to that described in International publication number WO 01/97893 A1 (Frater et al.), the content of which is hereby incorporated by cross-reference in its entirety.

[0057] Due to its location between the cushion 42 and the frame 38, the gusset portion 62 also acts to decouple the nozzles 17 mounted upon the soft cushion 42 from the rigid frame 38. This provides further flexibility within the patient interface which has the advantages previously described of allowing the interface to adjust to the geometry of different patients and allowing for any jaw or head movement during sleep. A further advantage of the gusset portion 62 is that it allows the face contacting portion, e.g., membrane 58, of the cushion 42 increased freedom to deform in accordance with the contours of the mouth region than does a direct connection between the cushion 42 and rigid frame 38. Thus the cushion 42 may 'wrap around' the mouth region as required.

[0058] The gusset portion 62 of the embodiment shown in figures 6a and 6b is a partial gusset portion in that it is arranged at the chin portion of the mouth covering chamber 40. Alternatively the gusset portion 62 may fit around the entire circumference of the rigid frame 38. An embodiment of this is shown in figures 7a-c. As can be seen from Fig. 7a, the embodiment includes an inlet swivel assembly 50, a frame 38, a gusset portion 62 and a soft cushion 42 with nozzles 17 mounted thereon.

[0059] Fig. 7b shows the components disassembled, although the swivel assembly 50 and frame 38 are shown in an assembled state that could be disassembled in an alternative embodiment. The headgear clips 60, cushion clip 56 and cushion 42 with gusset portion 62 can also be seen in Fig. 7b. The clip 56 may include one or more resilient tabs 57 that engage with corresponding recesses 59, one of which is shown on frame 38.

[0060] Two alternative cushions, 42A and 42B without gussets are displayed in Fig. 7b. It should be noted that each of the nozzles 17 on cushion 42B includes a simple mound rather than containing a single flexible pleat as do the nozzles on cushion 42 and cushion 42A. The nozzles 17 may also include a plurality of corrugations and in general the nozzles may take the form of a nasal puff as described in U.S. Patent No. 4,782,832 (Trimble et al), or as in other known nasal cannulae, such as prongs that extend into the nares. Further nozzle alternatives are described in U.S. Provisional Application No. 60/529,696, filed December 16, 2003 and entitled "Nasal Assembly."

[0061] Figures 7c-7f show an alternative embodiment of a patient interface assembled to a headgear assembly 31 via clip 60 that is selectively adjustable in a rotational sense with respect to yoke 31 attached to strap 30, as described in U.S. Patent Application No. 10/391,440, filed March 19, 2003, incorporated herein by reference in its entirety. Each clip 60 includes opposed arms 64 that may resiliently flex towards one another to allow engagement and disengagement of claws 66 formed on arms 64. The claws 66 may lockingly engage with corresponding structure or a receptacle 68 formed on or as part of frame 38. In this embodiment, the receptacle 68 may be moved, flexed or pivoted with respect to a portion 38a of the frame 38, e.g., along pivot axis 70. Fig. 7d shows the clips 60 in different angular positions.

[0062] Fig. 7e is an exploded view of clip 60, receptacle 68 and portion 38a of frame 38. The portion 38a may be attached to (e.g., via glue) or formed as an integral part of the frame 38. The receptacle 68 includes side chambers 68a for receiving claws 66 and a central chamber 68b for receiving central tab 61 of clip 60. The receptacle 68 may be attached to portion 38a, e.g., via a pin and slot assembly. For example, the receptacle 68 may include opposed arms 69 each including a pin 71. Each pin 71 can be received within an end 73 of a C-shaped channel 75. At least one of the arms 69 or the C-shaped channel 75 may flex to allow assembly and disassembly. Of course, other arrangements for allowing relative movement are possible.

[0063] Alternative headgear may be used, i.e., this embodiment is not limited to the headgear assembly shown in Fig. 7c. Vents 72 for the removal of excess carbon dioxide are shown in Fig. 7c. The vents 72 may be formed on an elastic insert, as described in U.S. Patent No. 6,561,190, incorporated herein by reference in its entirety. Fig. 7e shows an enlarged patient-side view of the cushion 42 in isolation.

[0064] Fig. 8 shows an alternative form of headgear with an occipital strap 74, a coronal strap 76 and a depending strap 78 that is routed to the top of the ears. The headgear straps 74, 76, 78 may be rigid or may be constructed from a laminated foam material such as Breath-O-Prene™ –. In one form the headgear straps may be constructed from a combination of a soft comfortable material, such as Breath-O-Prene and a stiffening yoke 28 constructed from a polymer, such as nylon, as described in International Patent Application PCT/AU03/00458. Angular adjustment between the rigid frame 38 and the headgear, such as that may be achieved via the arrangement shown in Fig. 7c.

[0065] Figures 9-12 show the patient interface supported by spectacles-type headgear 80. One strap 82 is used as a hook mechanism behind the ear. The strap 82 may be extended to wrap

around the head and apply a force inwards towards the head, as shown in Fig. 9, or the wrap around portion may be eliminated as shown in Fig. 10. Fig. 11 shows an additional stabilizing band 84 around the neck. The headgear straps may be formed of any suitable material such as textile, plastic or semi-rigid assemblies. The headgear assembly has the advantage that it covers the minimum head area and therefore is more comfortable than many traditional designs. In order to improve patient comfort, the headgear may also require adjustment to suit the head circumference and ear height. It may also be applied to alternative forms of patient interface such as nasal prongs or nose masks.

[0066] Advantages of illustrated preferred embodiments may include:

- reducing significantly the bulk required to form an effective nasal and oral seal. This has the advantage of creating a less intrusive patient interface that significantly reduces the problems of patient claustrophobia. The removal of the requirement to seal around the nasal bridge provides the opportunity for the patient to wear spectacles. In addition this removes the danger of leaks affecting the sensitive eye region, thereby reducing the possibility of creating conjunctivitis style problems.
- reducing the force (headgear tension) required to maintain the seal as compared to current full face masks in the prior art. The force is reduced due to the reduction in the effective area of the cushion on to the face. As a result, there is less area over which the pressure inside the patient interface acts and the resultant headgear tension is reduced.
- improving seal as it avoids the nose bridge region where leak commonly occurs, thus the force required to deform the cushion and effect a seal is also reduced. The reduction in the headgear tension and cushion to face force would substantially reduce the discomfort to a patient.

[0067] The reduction in the area of the face across which a seal must be formed allows a single size or shape to fit a wider range of patient geometry. This is particularly advantageous for a clinician since the patient interface is both easier to fit to a new patient and potentially more forgiving of fitting errors. The independent nature of the chambers due to the flexible connection, also allows for some movement of the face during the night without loss of seal. This leads to far more stability than conventional single chamber full face masks.

[0068] The provision of flexibility allows the seal to remain throughout jaw and head position movement as well as providing adjustment for the different geometry of a wide range of patients. The task of fitting varying patient geometry is made easier by the removal of the need to seal around the complex form of the nasal bridge which is found in most of the prior art masks that seal both the nasal and oral passages. The lack of seal around the nasal bridge also allows the patient to wear spectacles.

[0069] Although the invention has been described with reference to the illustrated embodiments, it is to be understood that the illustrated embodiments are merely illustrative of the application of the principles of the invention. Numerous modifications may be made therein and other arrangements may be devised without departing from the spirit and scope of the invention.

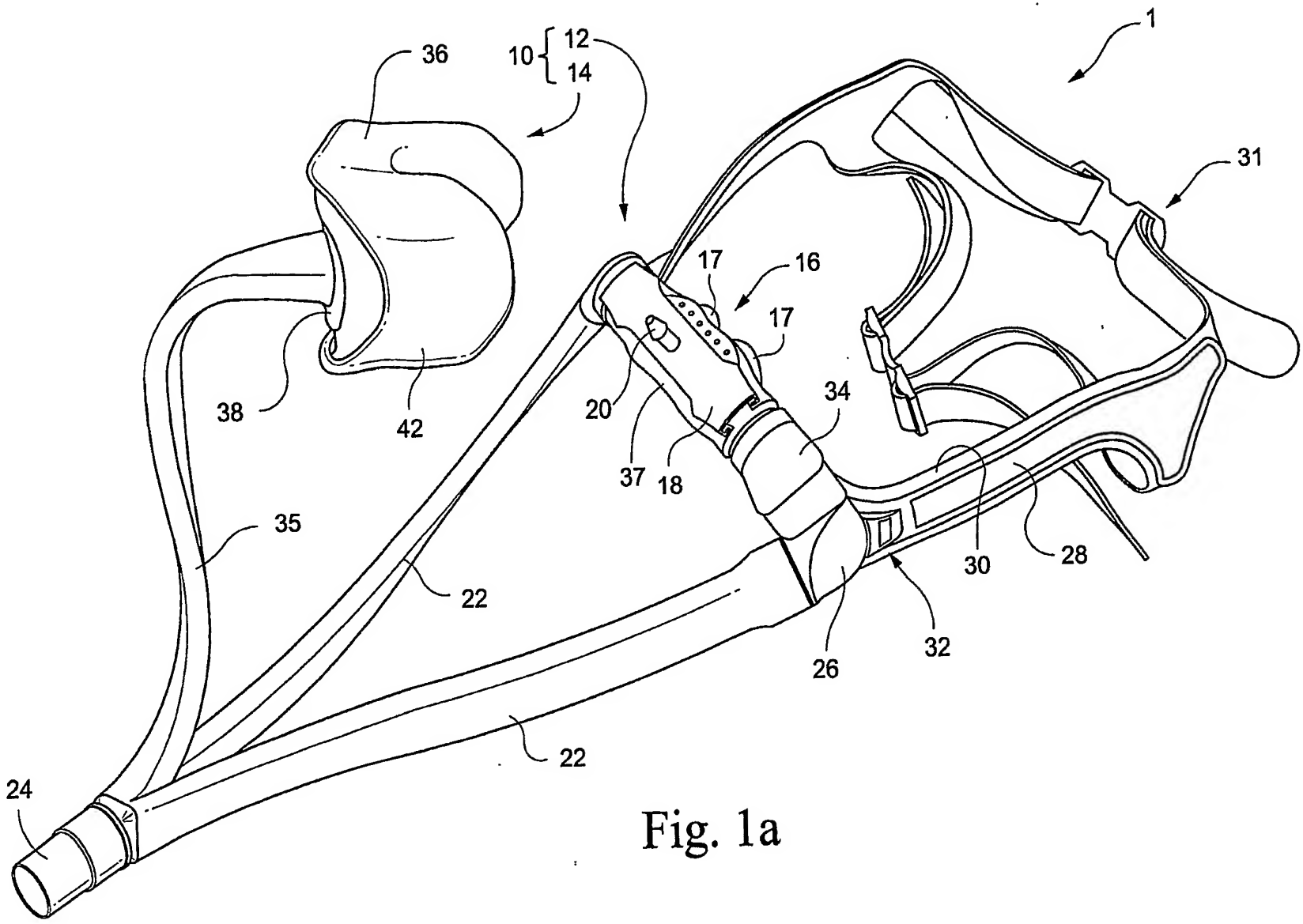

Fig. 1a

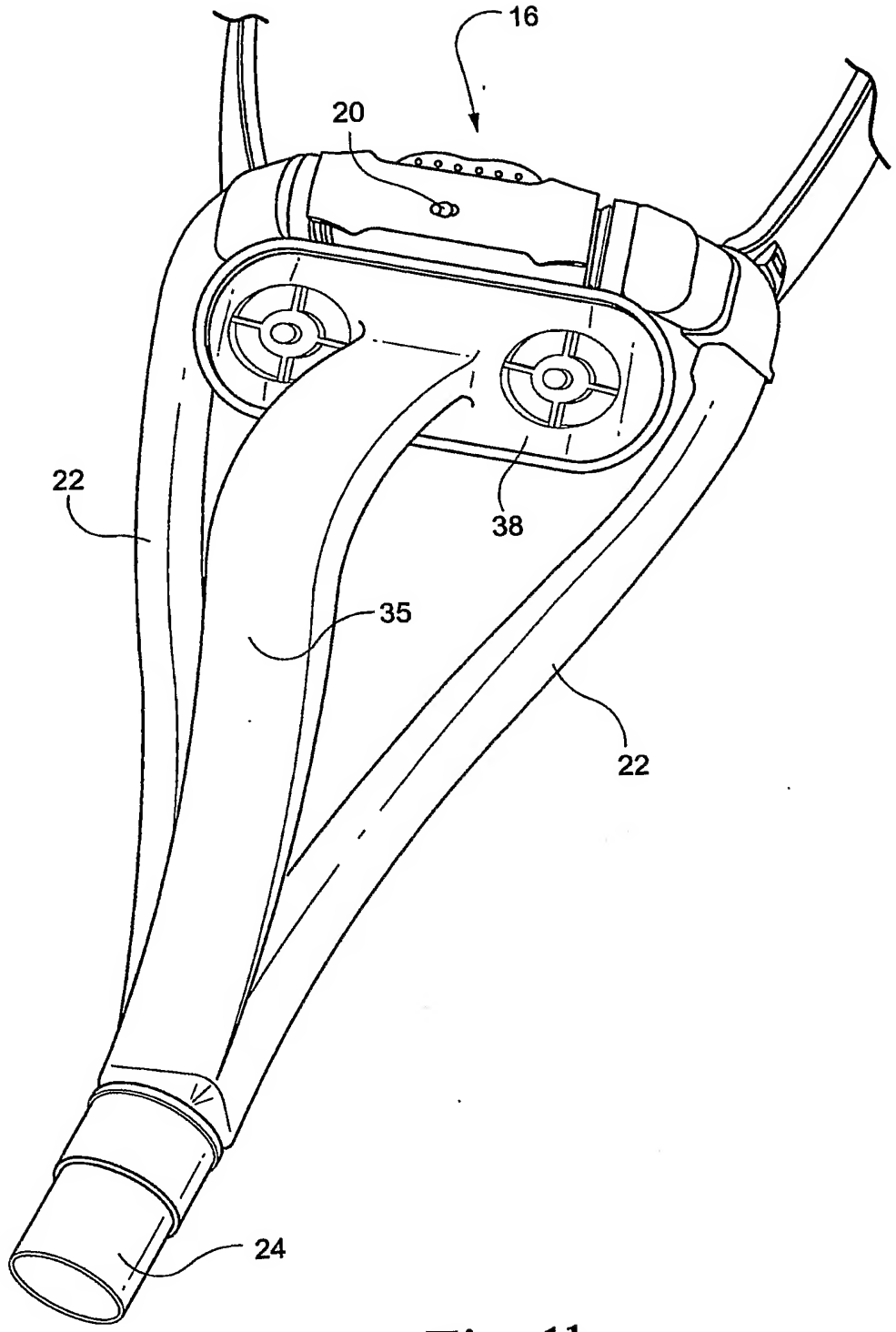

Fig. 1b

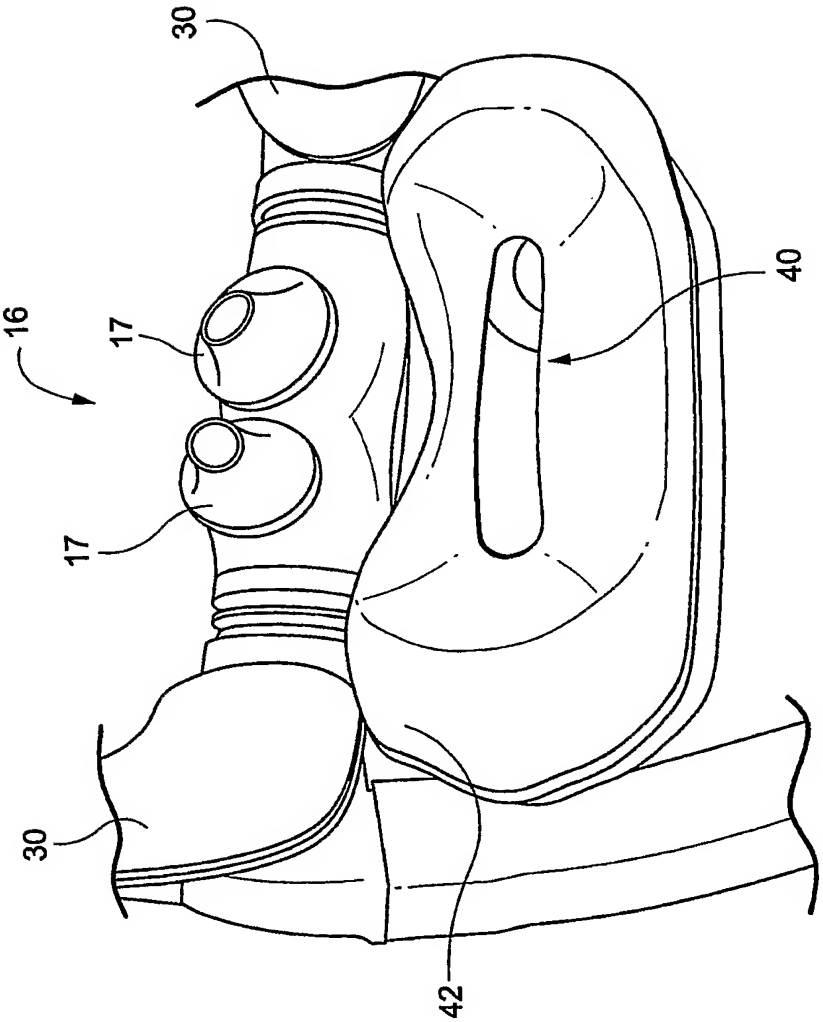

Fig. 1c

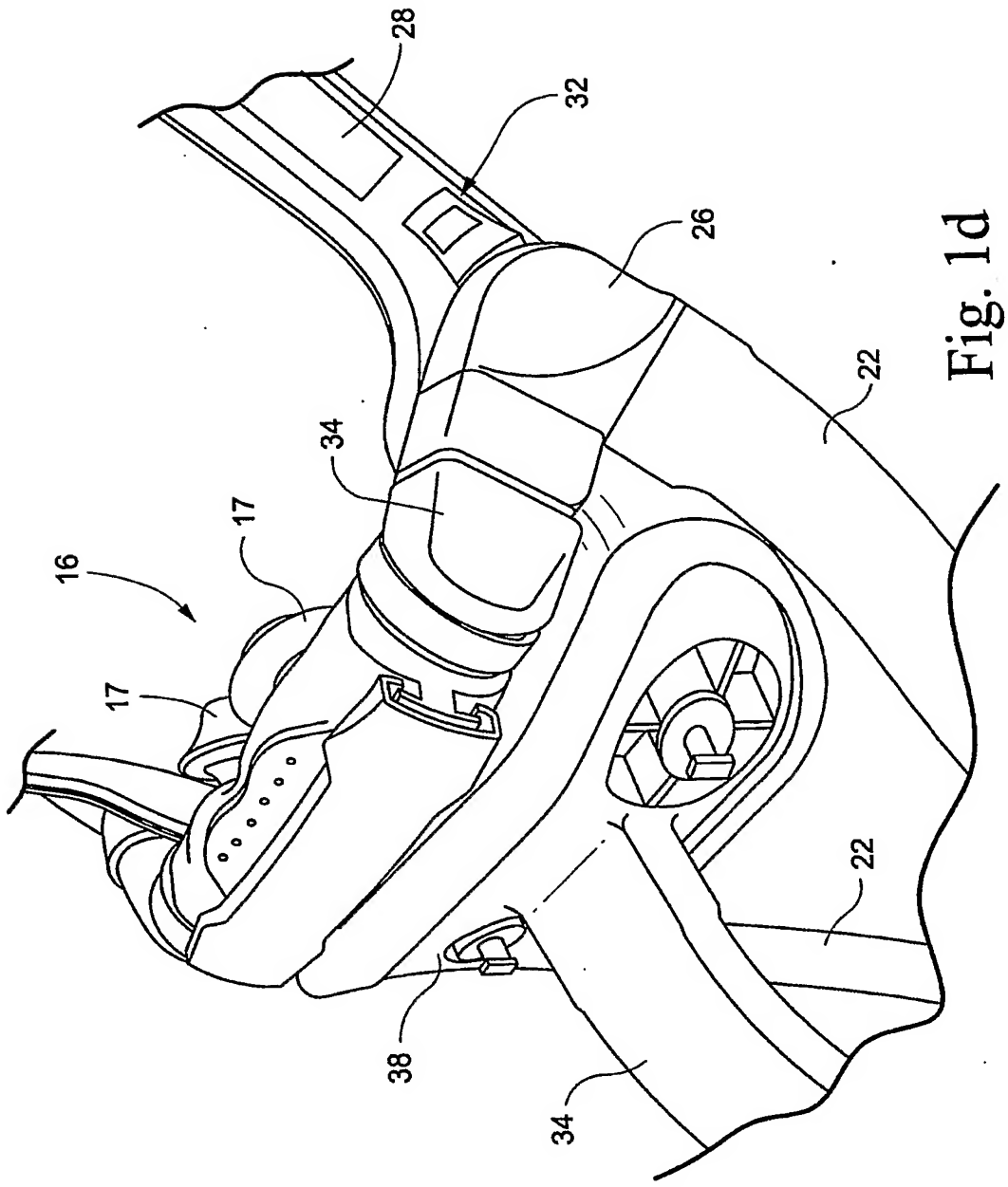

Fig. 1d

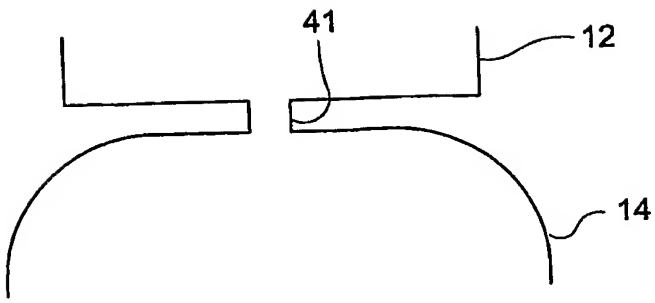

Fig. 1e

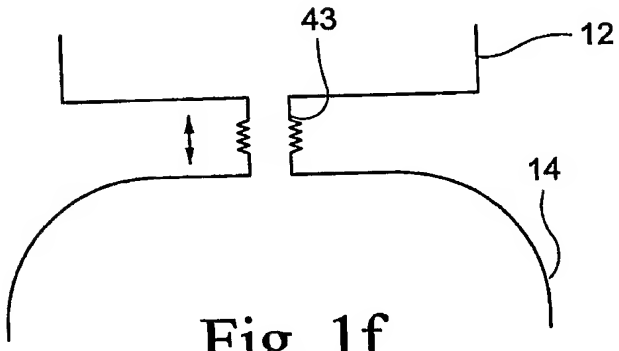

Fig. 1f

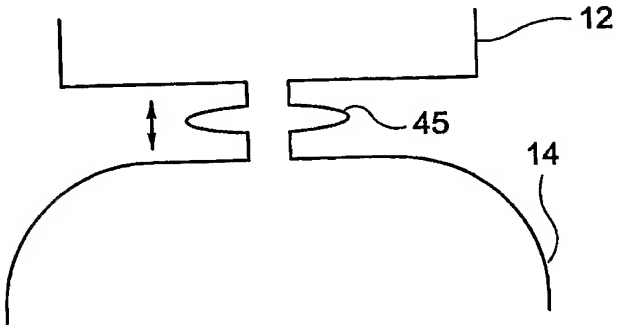

Fig. 1g

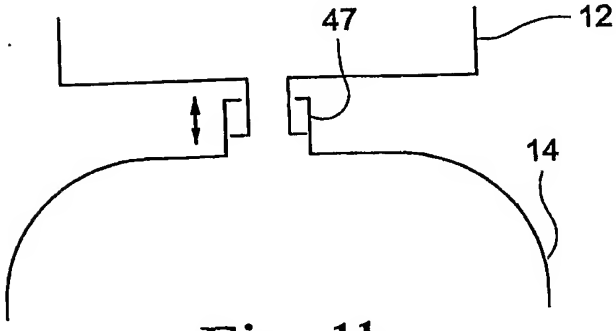

Fig. 1h

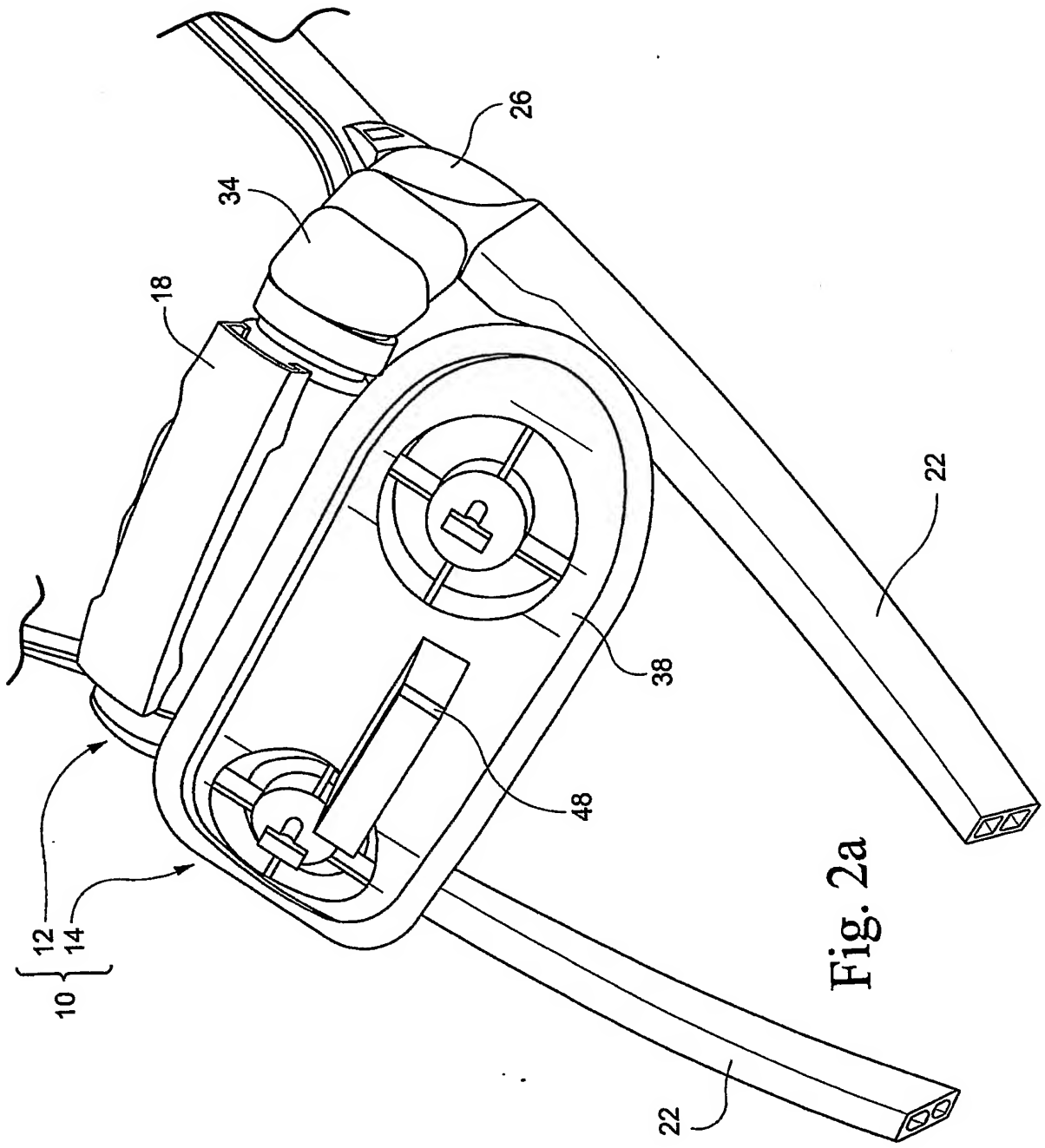

Fig. 2a

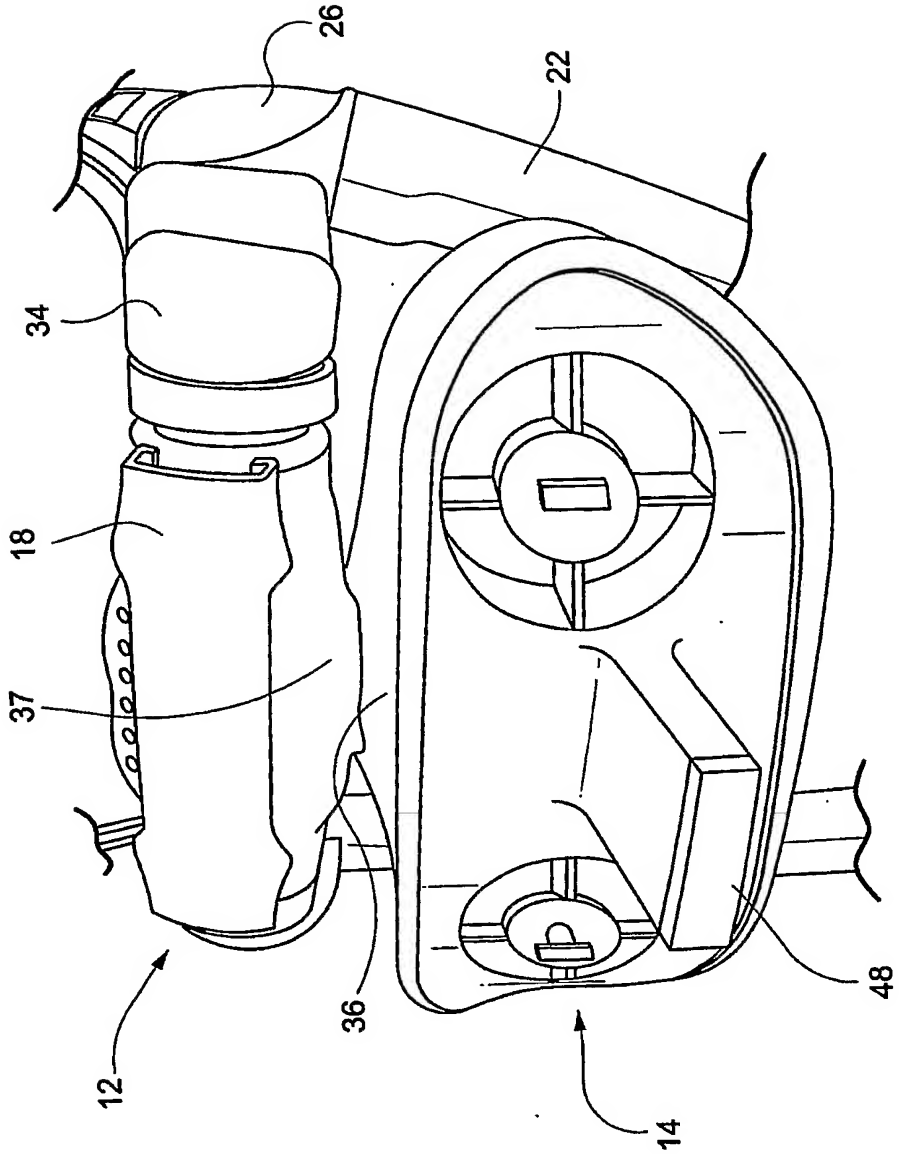

Fig. 2b

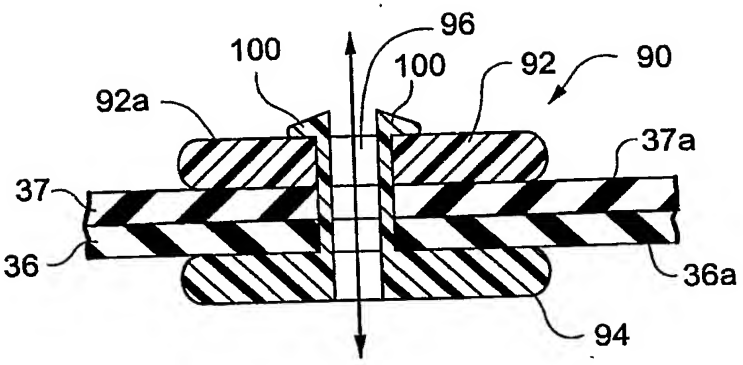

Fig. 2c

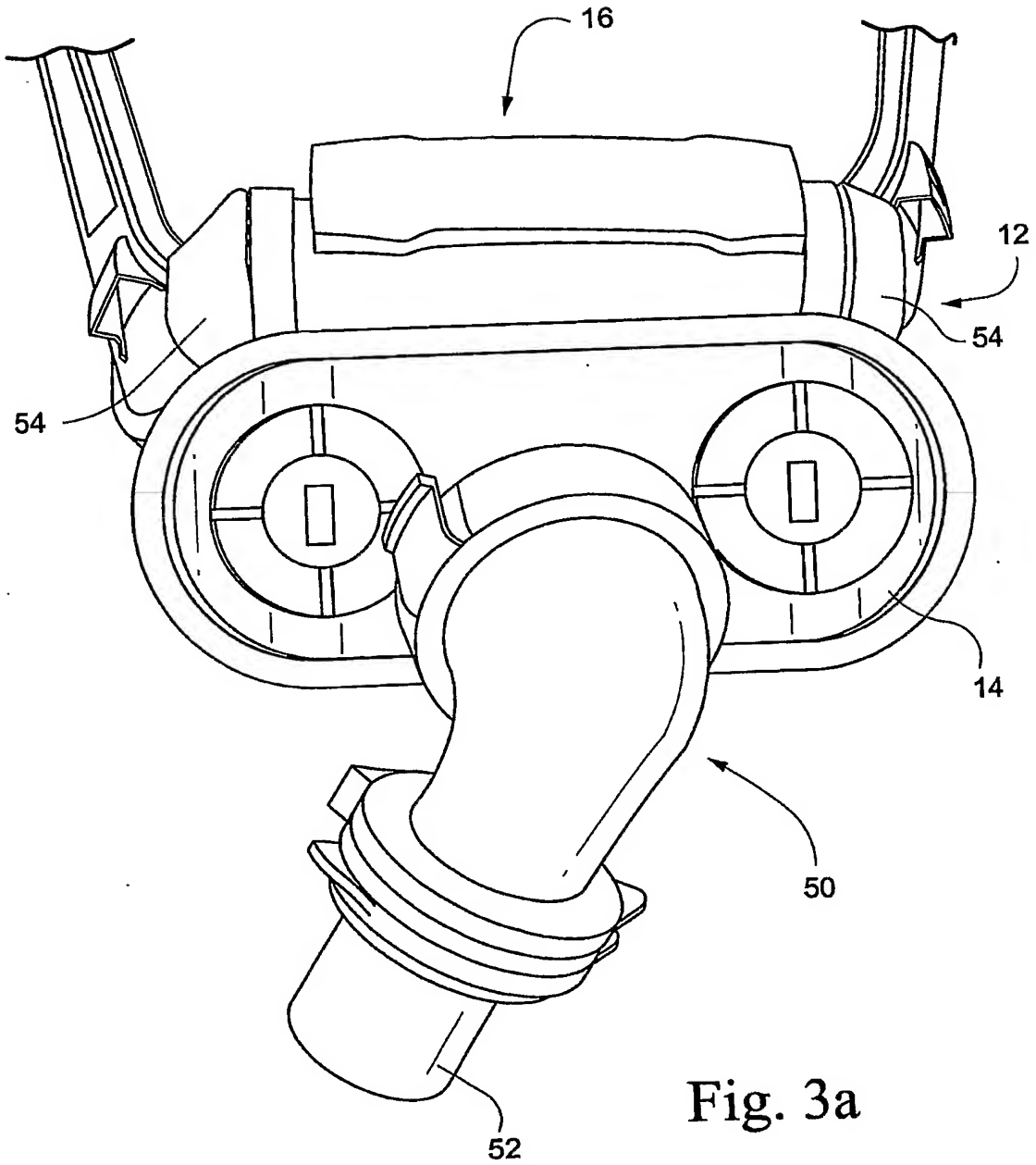

Fig. 3a

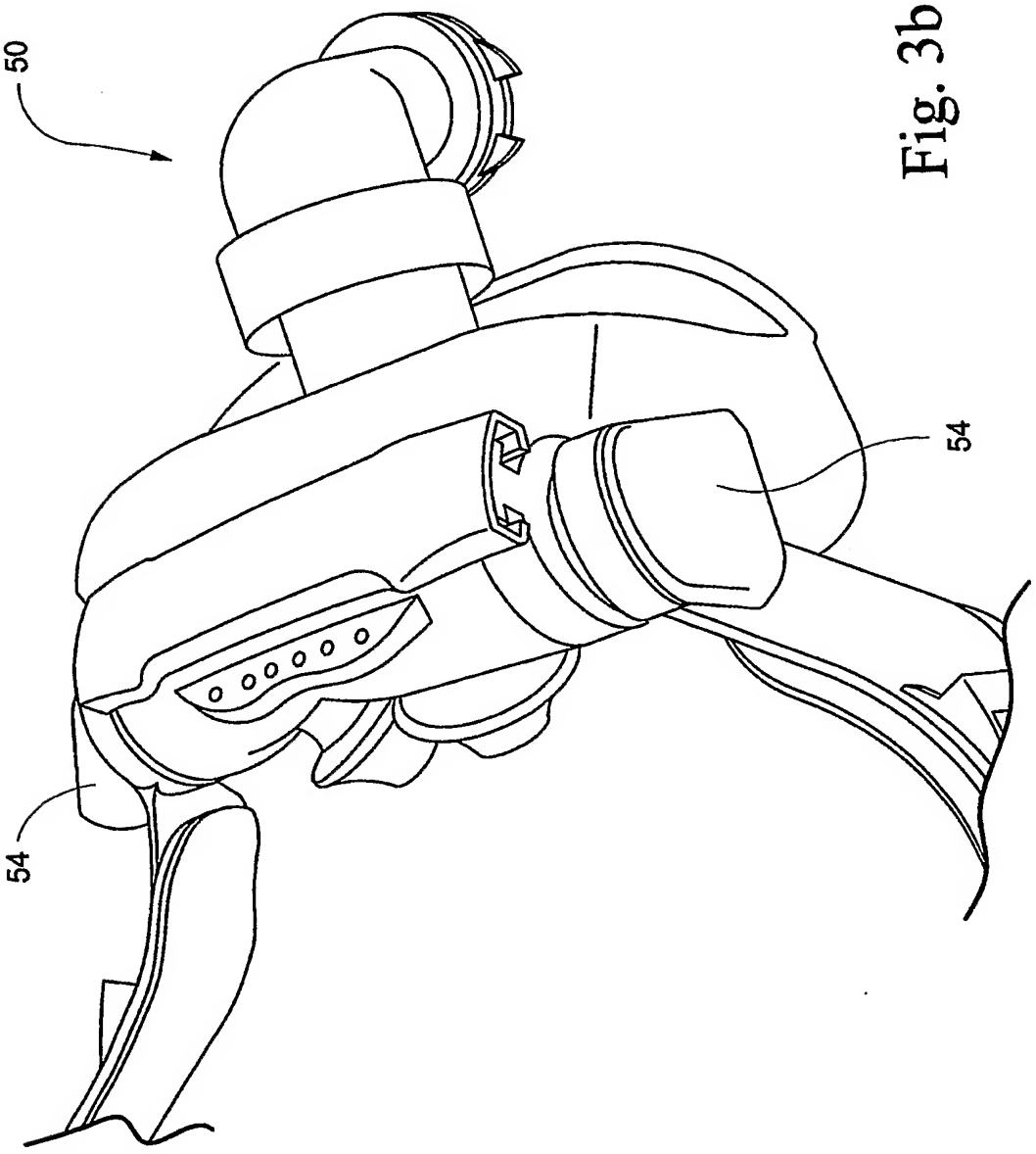

Fig. 3b

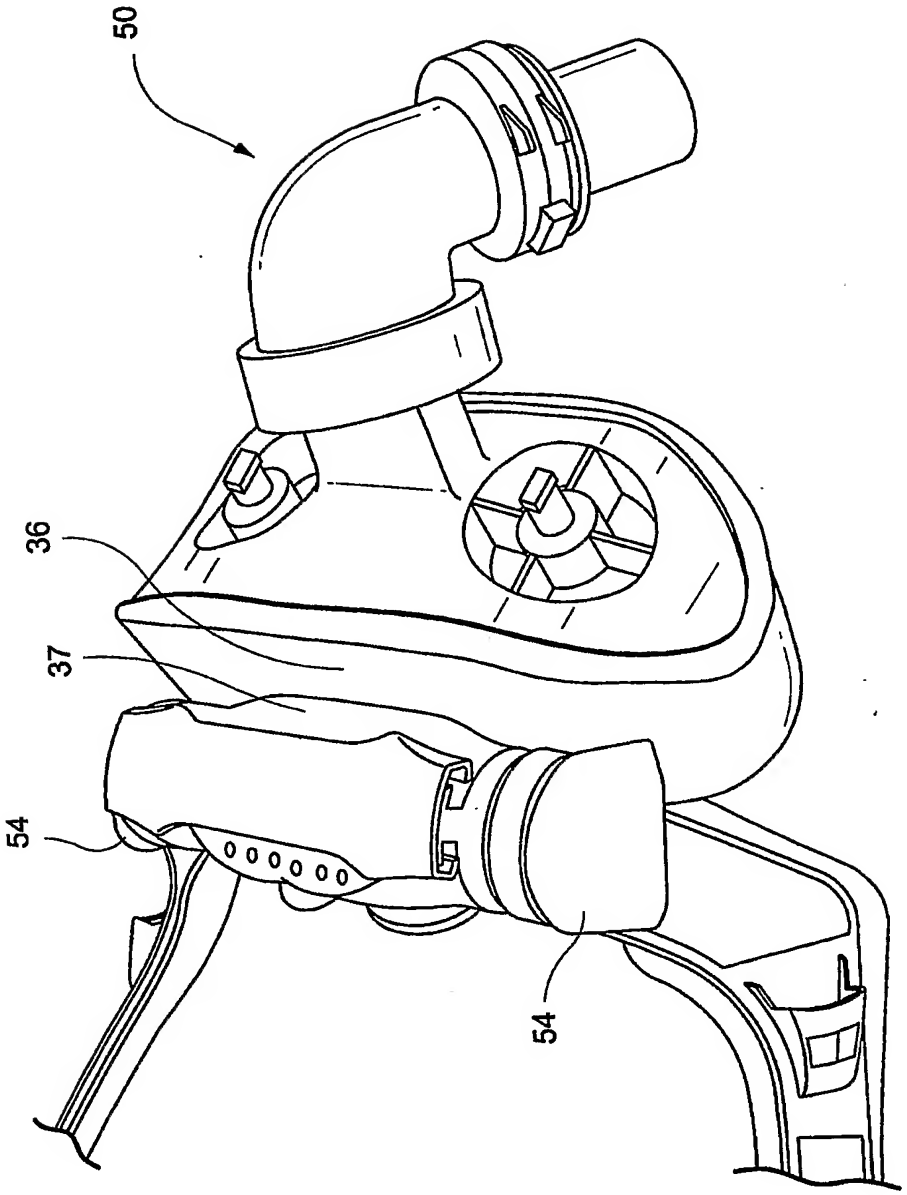

Fig. 3c

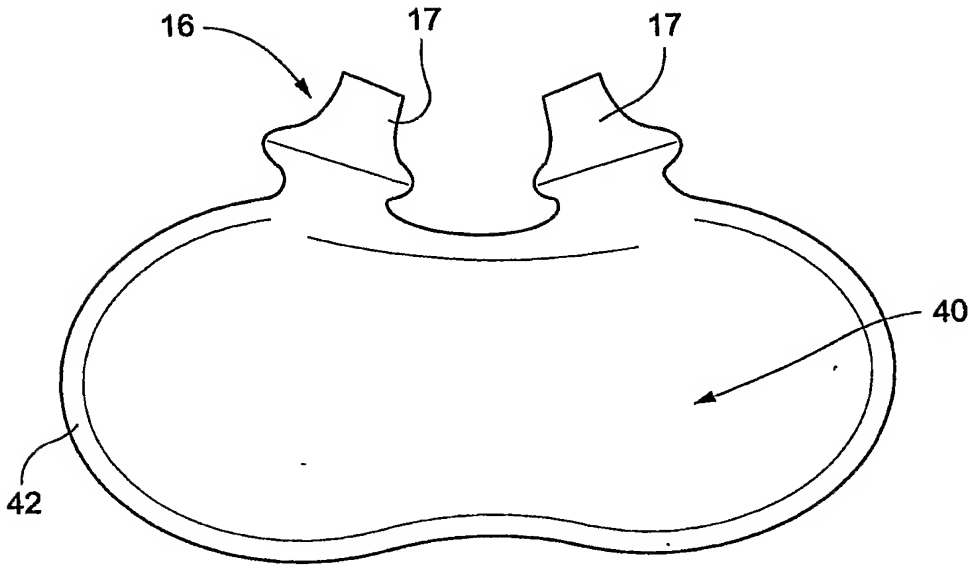

Fig. 4a

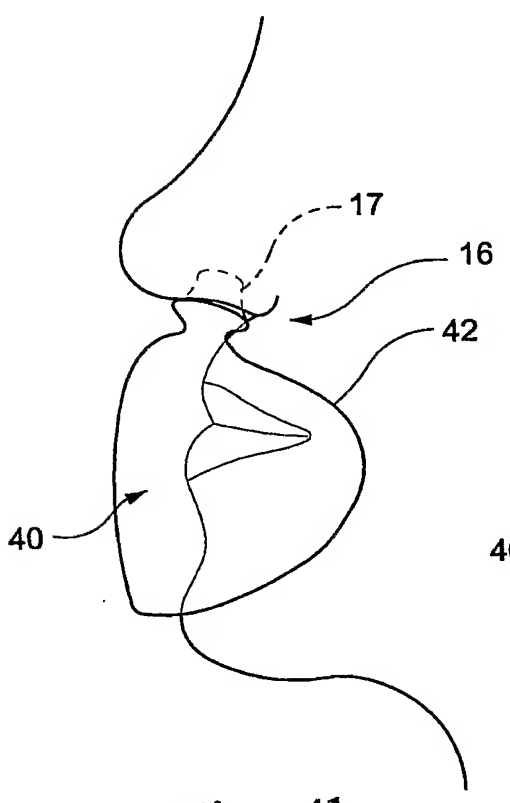

Fig. 4b

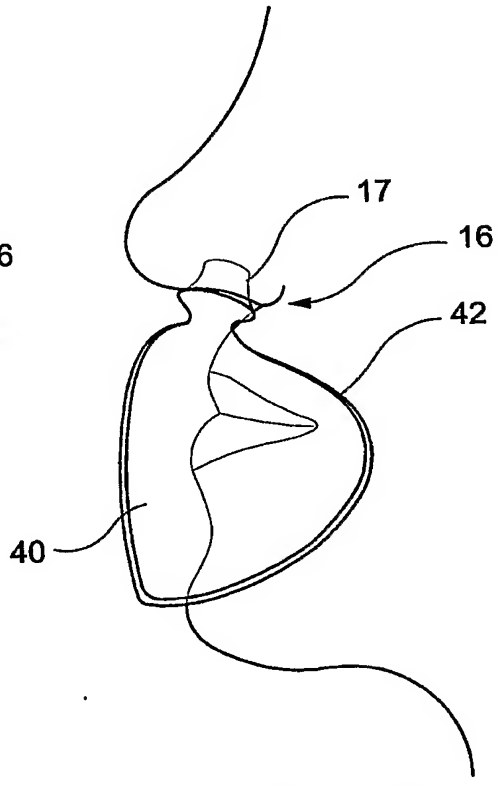

Fig. 4c

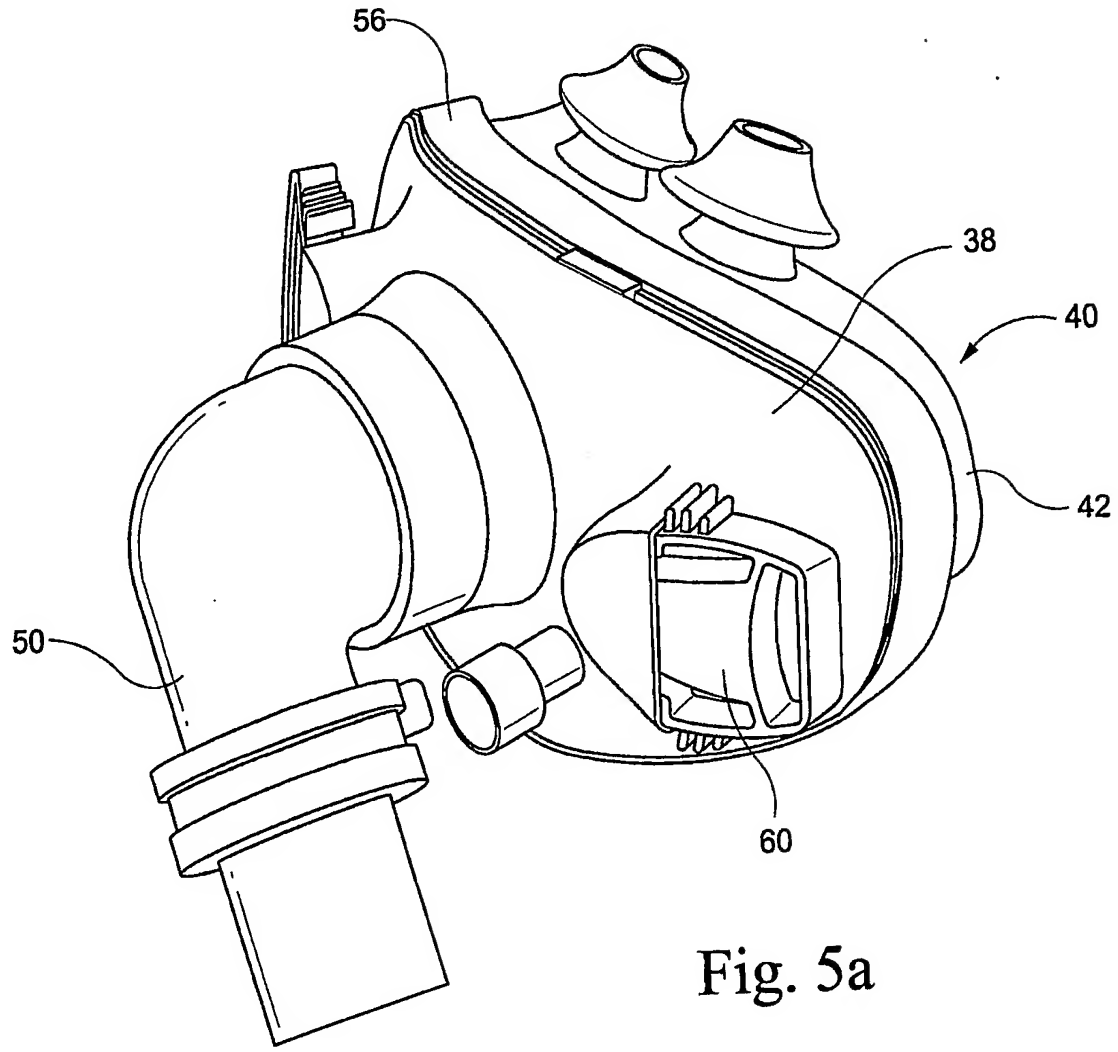

Fig. 5a

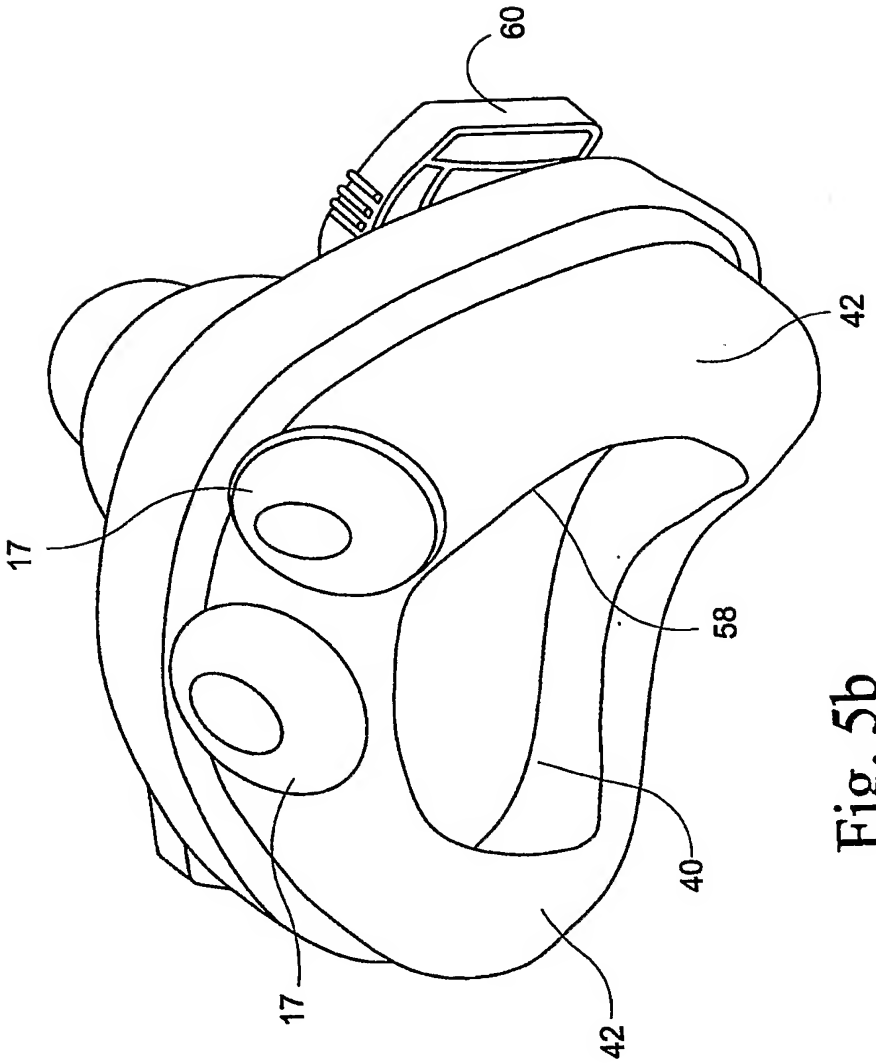

Fig. 5b

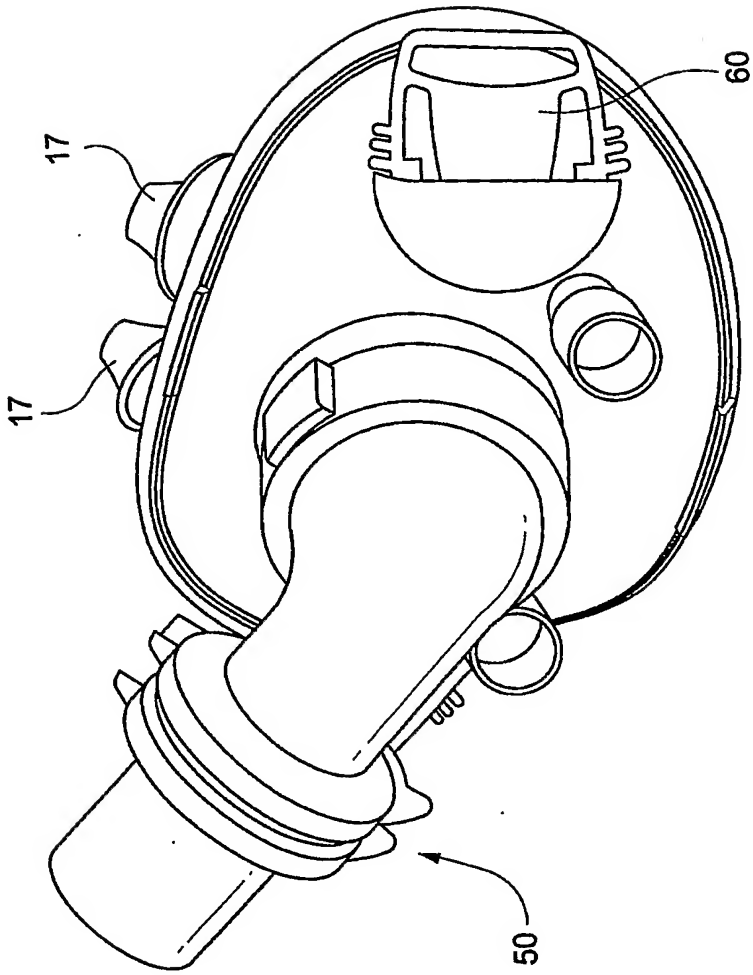

Fig. 5c

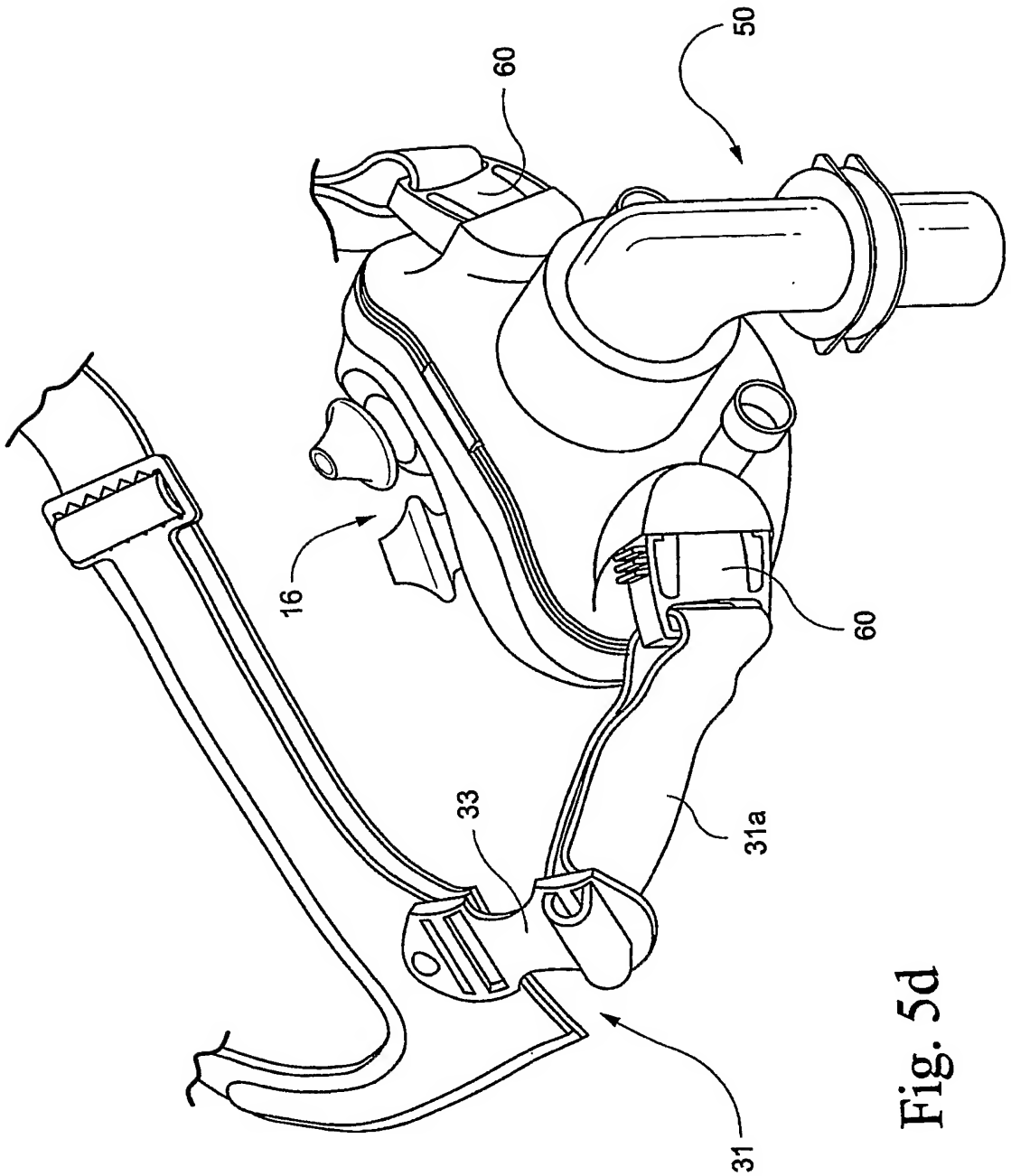

Fig. 5d

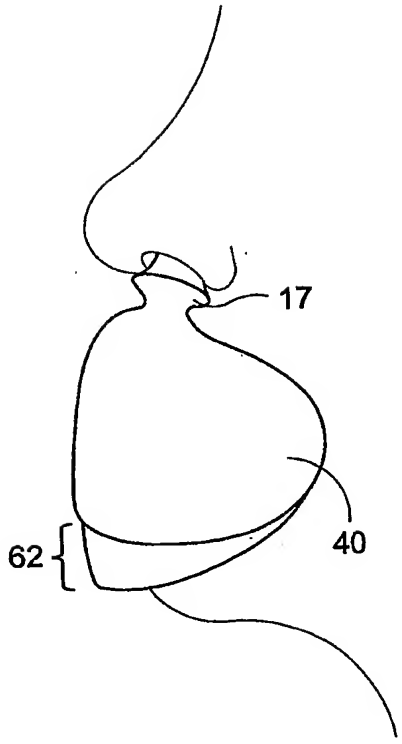

Fig. 6a

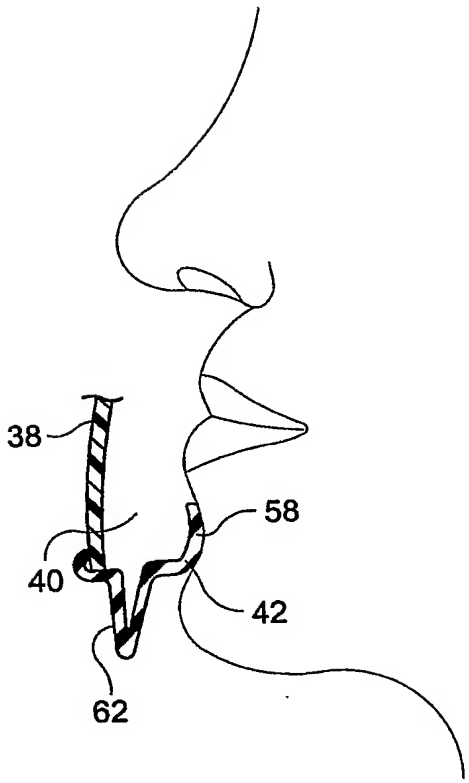

Fig. 6b

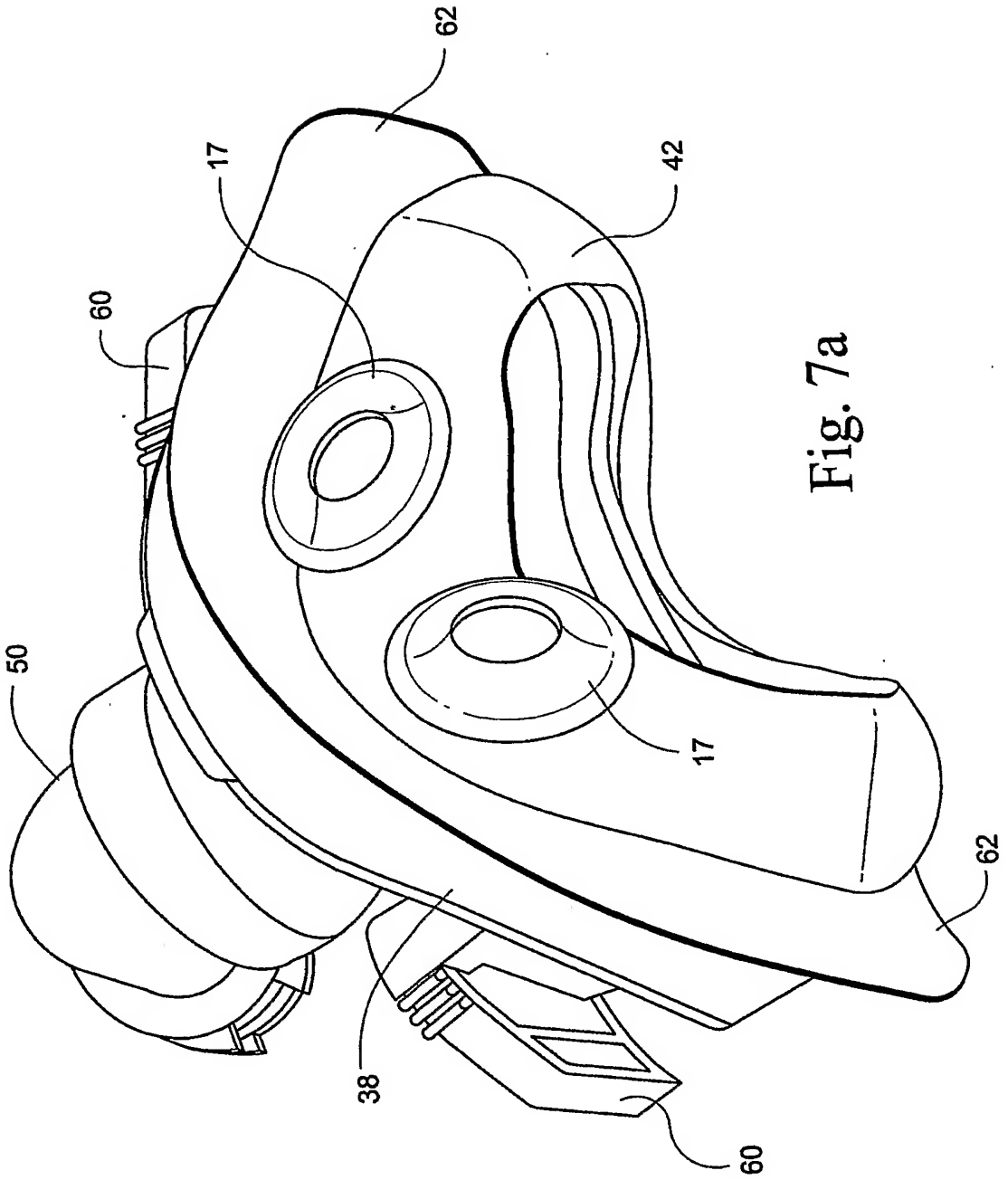

Fig. 7a

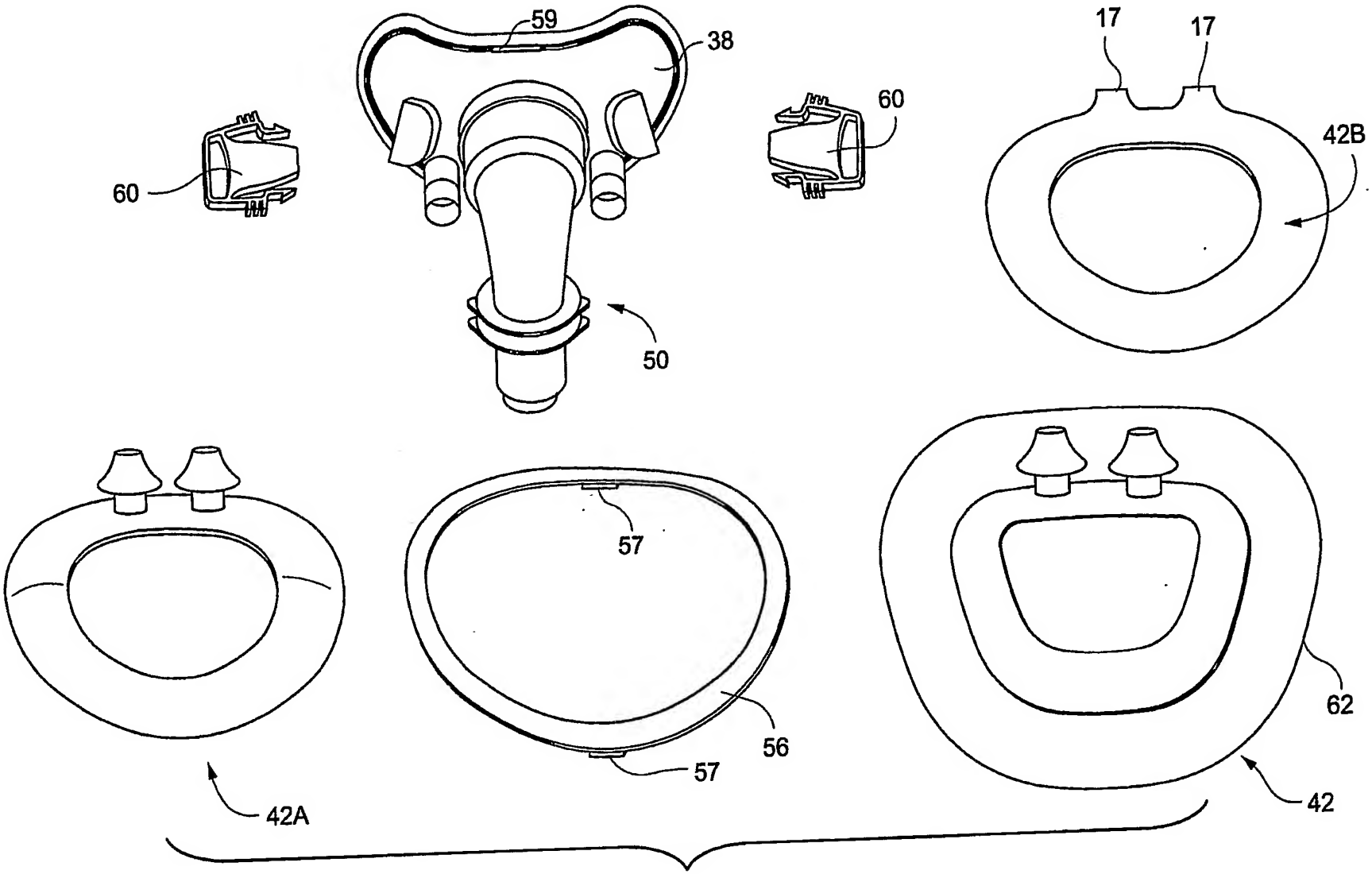

Fig. 7b

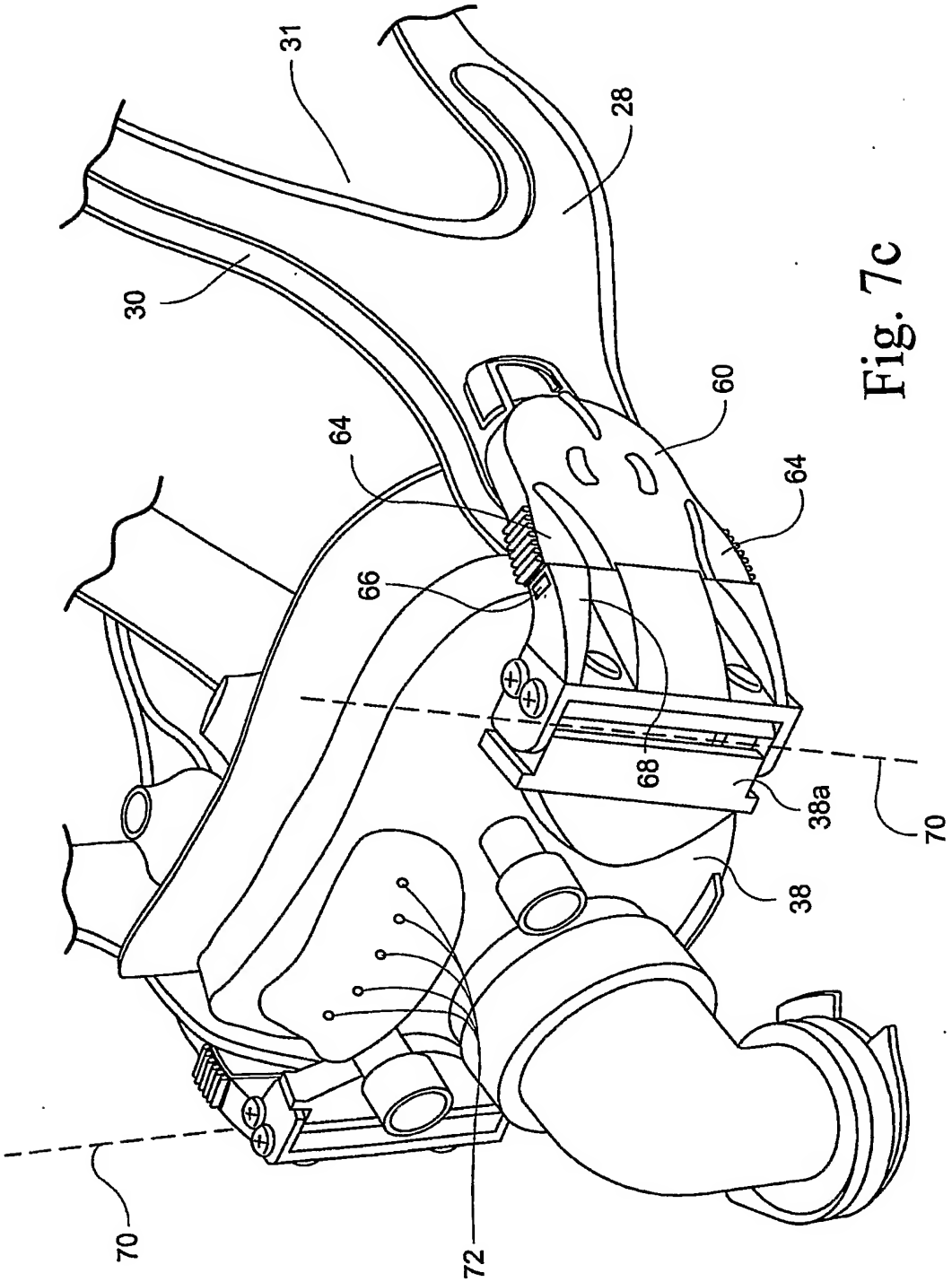

Fig. 7c

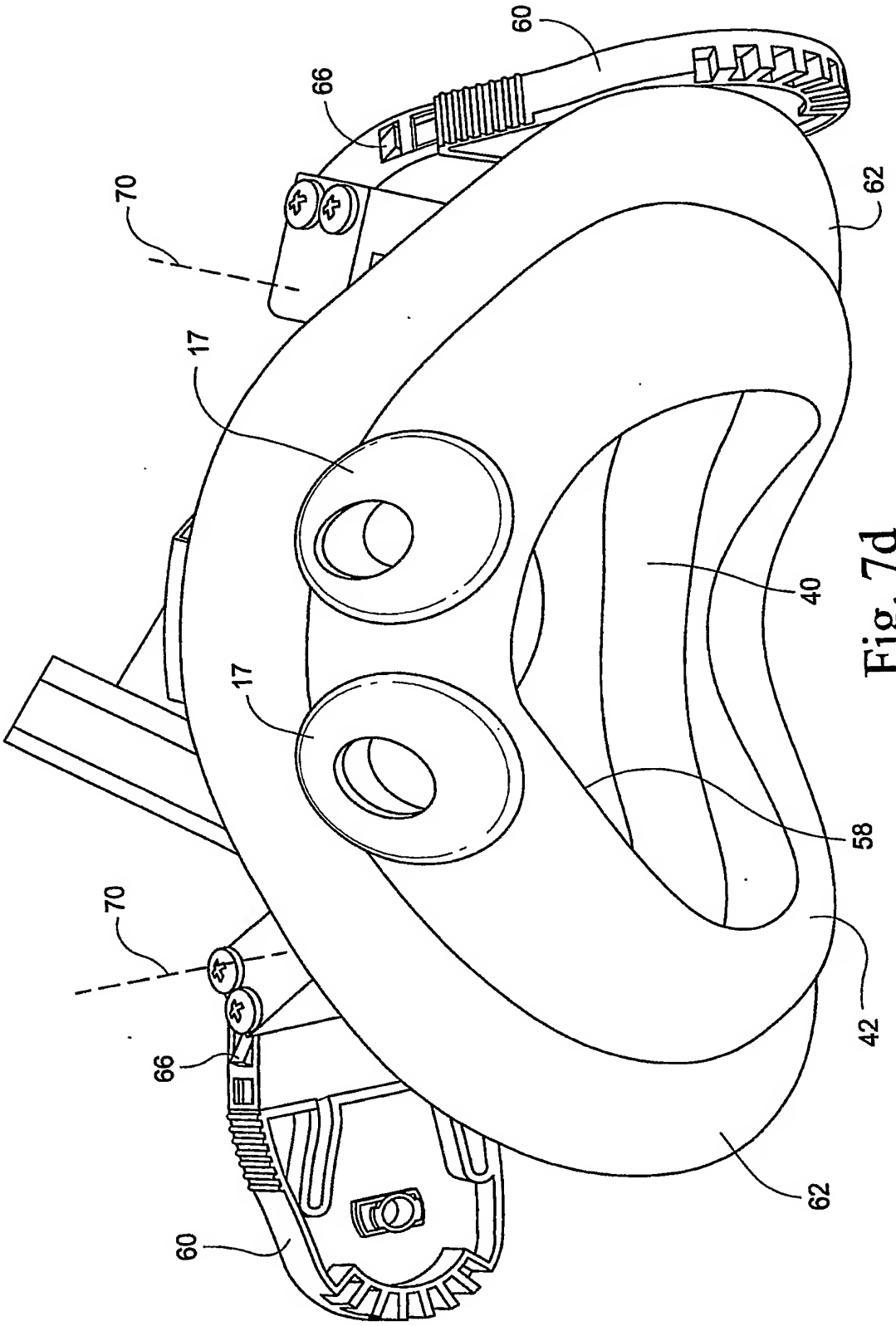

Fig. 7d

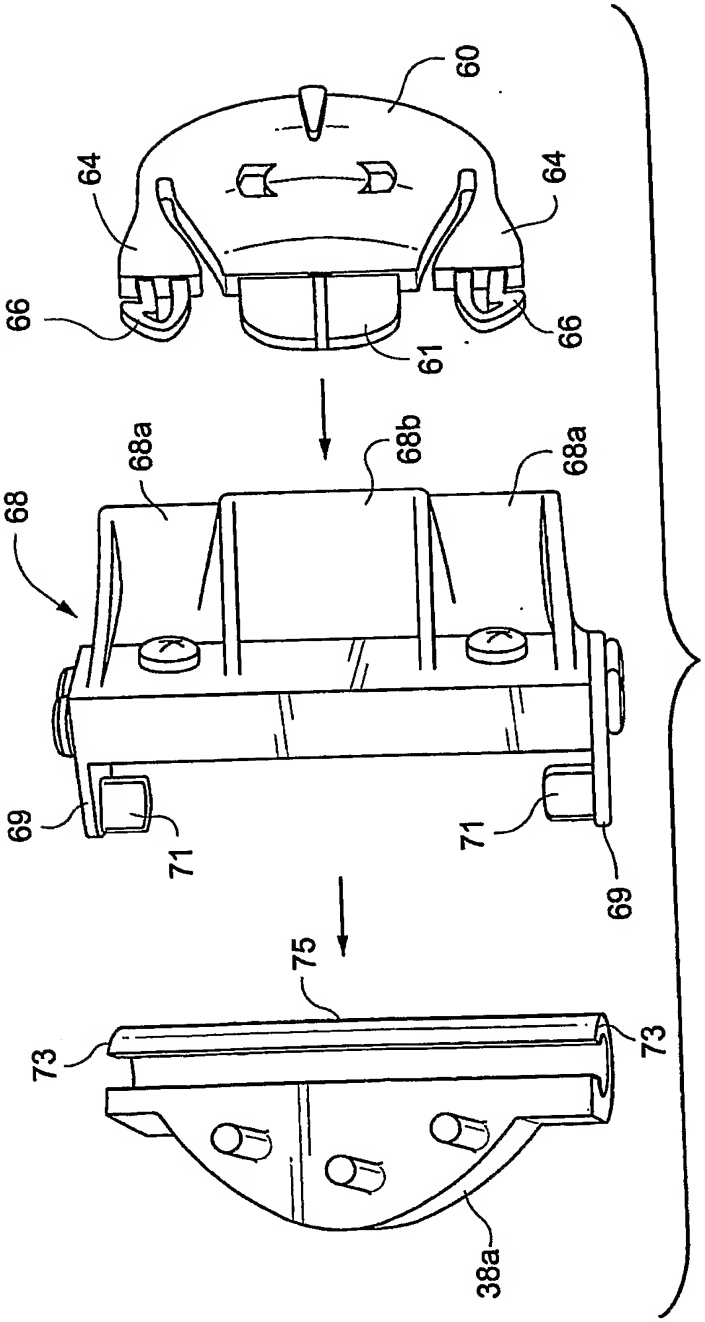

Fig. 7e

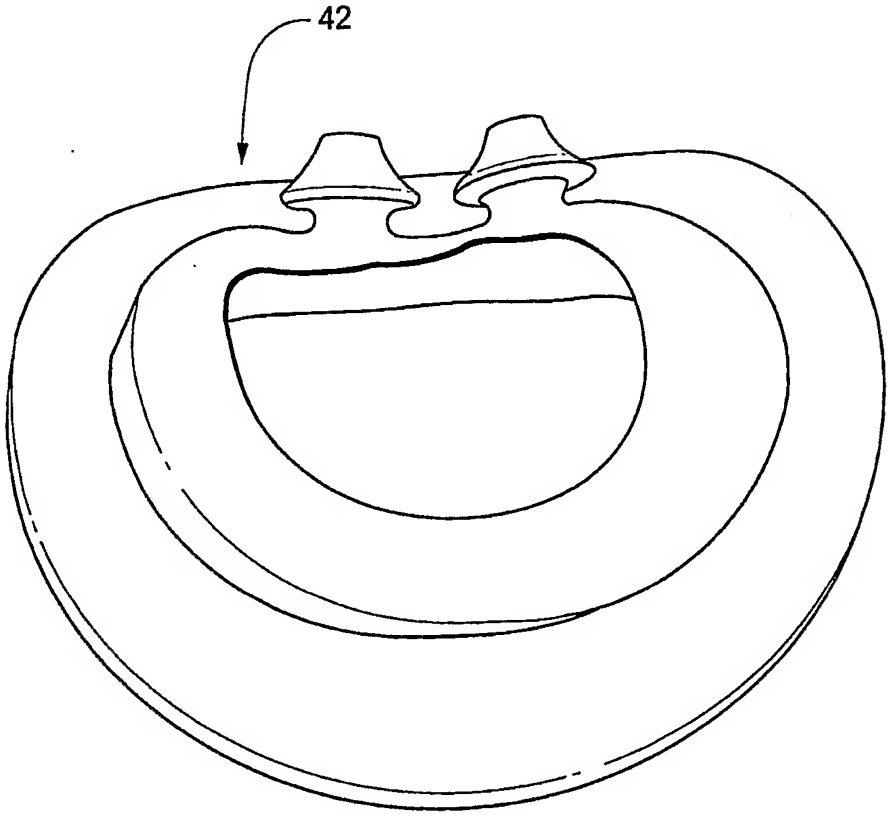

Fig. 7f

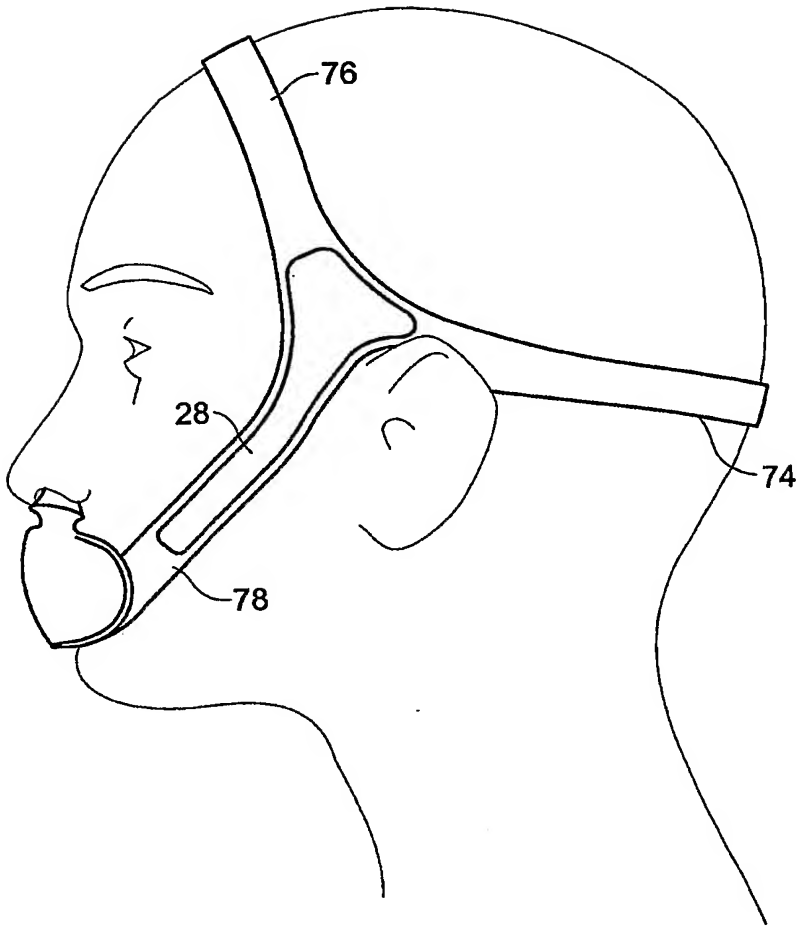

Fig. 8

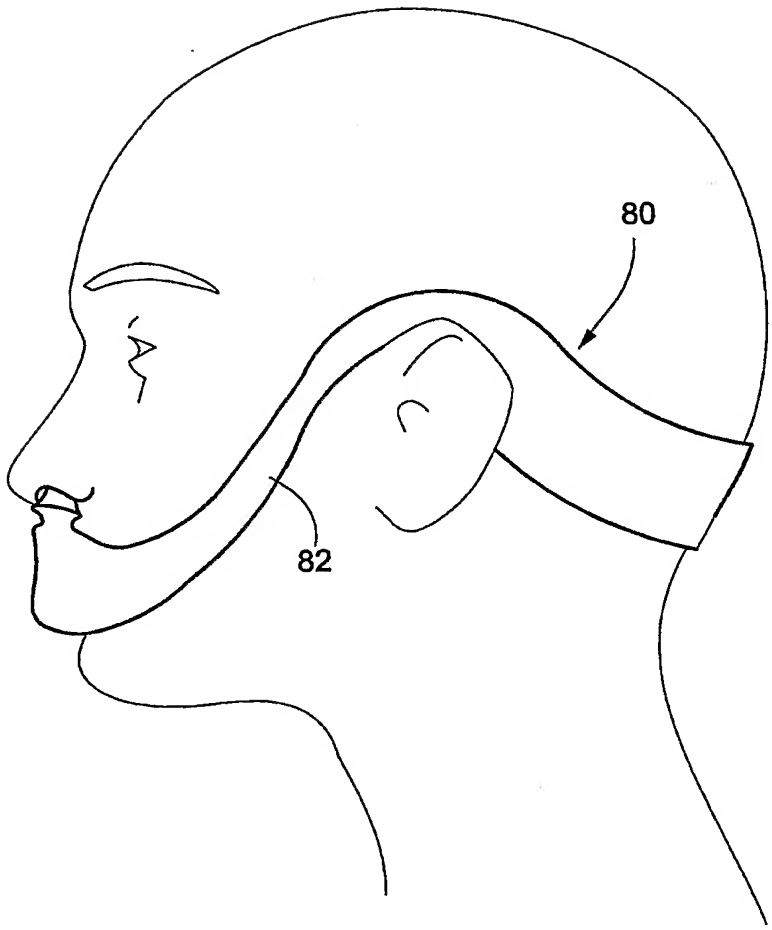

Fig. 9

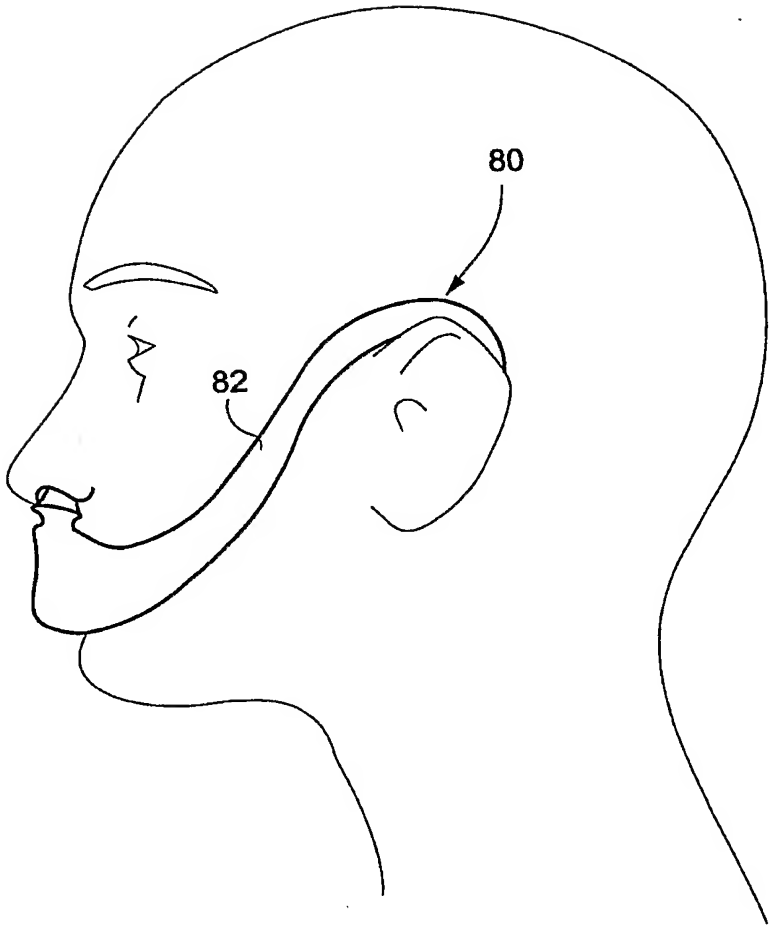

Fig. 10

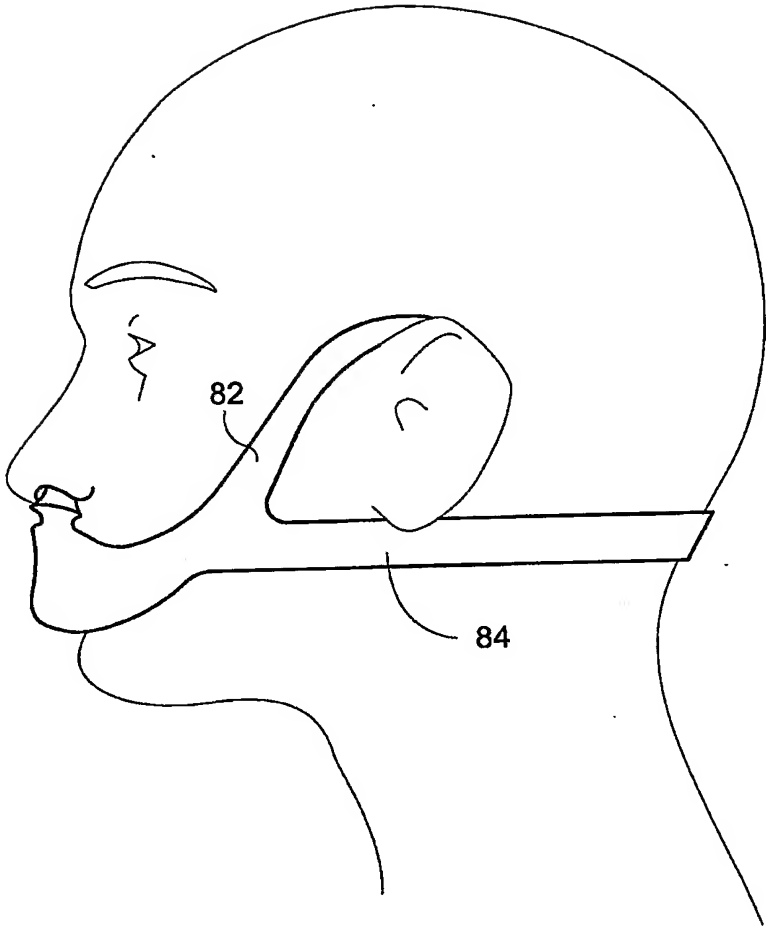

Fig. 11

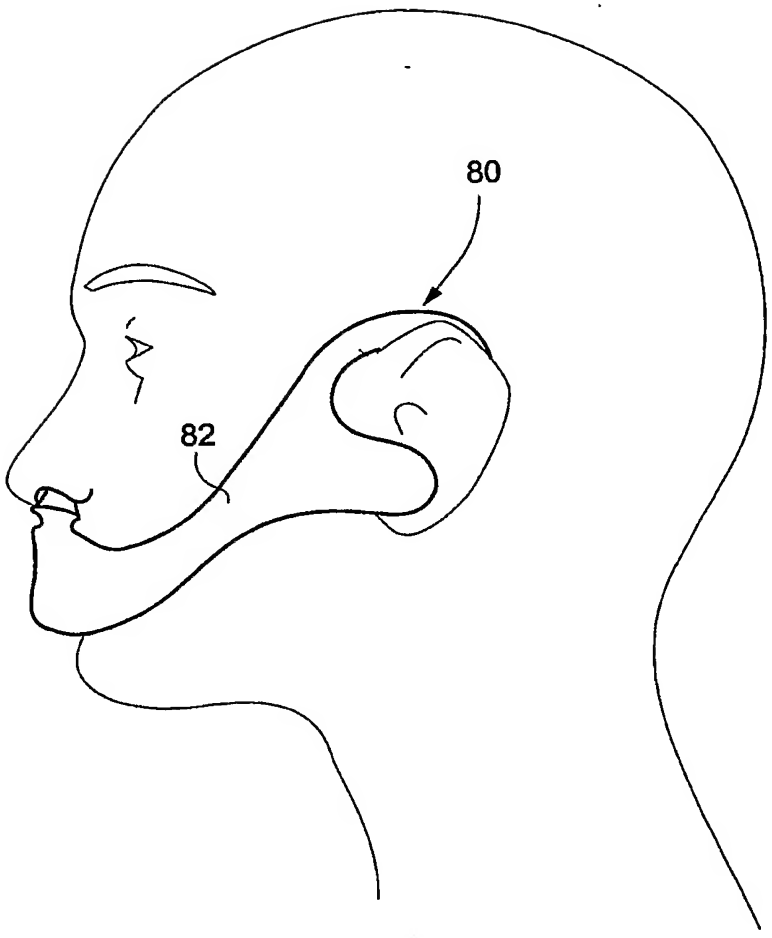

Fig. 12